

University of Dundee

DOCTOR OF PHILOSOPHY

**Increasing Physical Activity in Omani Adult Patients with Type 2 Diabetes Attending Primary Health Care Facilities, MUSCAT**

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**INCREASING PHYSICAL ACTIVITY  
IN OMANI ADULT PATIENTS WITH  
TYPE 2 DIABETES ATTENDING  
PRIMARY HEALTH CARE  
FACILITIES, MUSCAT**

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## **Declaration**

I hereby declare that the contents of this thesis are my own, have not been presented or accepted in any previous application for a degree, and are a true record of the work carried out by myself unless otherwise stated. All quotations have been distinguished by quotation marks and all sources of information acknowledged.

Thamra S Alghafri

January ~2019

## List of publications

**ALGHAFRI, T. S.**, ALHARTHI, S. M., AL-FARSI, Y., ALRAWAHI, A. H., BANNERMAN, E., CRAIGIE, A. M. & ANDERSON, A. S. 2018. 'MOVEdiabetes': a cluster randomized controlled trial to increase physical activity in adults with type 2 diabetes in primary health in Oman. *BMJ Open Diabetes Research & Care*, 6.

**ALGHAFRI, T.**, ALHARTHI, S. M., AL FARSI, Y. M., BANNERMAN, E., CRAIGIE, A. M. & ANDERSON, A. S. 2017a. Perceived barriers to leisure time physical activity in adults with type 2 diabetes attending primary healthcare in Oman: a cross-sectional survey. *BMJ Open*, 7.

**ALGHAFRI, T. S.**, ALHARTHI, S. M., AL-BALUSHI, S., AL-FARSI, Y., AL-BUSAIDI, Z., BANNERMAN, E., CRAIGIE, A. M. & ANDERSON, A. S. 2017b. Health professionals' perceptions about physical activity promotion in diabetes care within primary health care settings in Oman. *Heliyon*, 3, e00495.

**ALGHAFRI, T. S.**, ALHARTHI, S. M., AL-FARSI, Y., BANNERMAN, E., CRAIGIE, A. M. & ANDERSON, A. S. 2017c. Correlates of physical activity and sitting time in adults with type 2 diabetes attending primary health care in Oman. *BMC Public Health*, 18, 85.

**ALGHAFRI, T. S.**, ALHARTHI, S. M., AL-FARSI, Y. M., CRAIGIE, A. M., MCLEOD, M. & ANDERSON, A. S. 2017d. Study protocol for "MOVEdiabetes": a trial to promote physical activity for adults with type 2 diabetes in primary health care in Oman. *BMC Public Health*, 17, 28.

## Recent conference presentations from this thesis

**ALGHAFRI, T. S.** (December 2018). Acceptability of the “MOVEdiabetes” programme: findings from a cluster randomised controlled trial to increase physical activity in adults with type 2 diabetes in Oman. *14th Annual Scientific Meeting of the UK Society for Behavioural Medicine (UKSMB), Birmingham, UK.*

**ALGHAFRI, T. S.** (October 2018). “MOVEdiabetes” A Trial to Promote Physical Activity for Adults with Type 2 Diabetes in primary health care, Oman. *The 7th International Society for Physical Activity and Health Congress (ISPAH), London.*

**ALGHAFRI, T. S.** (May 2018). Ways to integrate PA in primary health care in Muscat. *Hai Almina health centre, Oman.*

**ALGHAFRI, T. S.** (February 2018). Promoting physical activity using behaviour change techniques in the management of type 2 diabetes in primary health care, Oman. *Diabetes and endocrine centre in Oman.*

**ALGHAFRI, T. S.** (December 2017): Health care professional perceptions about physical activity promotion in diabetes care within primary health care settings in Oman. *14th Annual Scientific Meeting of the UK Society for Behavioural Medicine (UKSMB), Liverpool, UK.*

**ALGHAFRI, T. S.** (December 2017). Perceived barriers to leisure time physical activity in adults with type 2 diabetes attending primary health care in Oman: a cross-sectional survey. *The international diabetes federation-IDF, Abu Dhabi, UAE.*

**ALGHAFRI, T. S.** (August 2015). A practical guide to integrate physical activity in primary health care in EMRO region organized by *World Health Organization, Cairo, Egypt.*

**Abstract**

The prevalence of diabetes is increasing globally including in countries of the Gulf Cooperation Council namely Oman. Physical activity has been recognized as a “cornerstone” in the management of diabetes, yet many individuals with diabetes fail to reach the recommended levels of at least 150 min/week of moderate to vigorous physical activity.

The aims of this PhD thesis were to explore current levels of physical activity in this population, investigate barriers to activity and perceptions about a culturally effective, practical and acceptable approaches for activity promotion within local diabetes primary care in Oman. Using these findings, a physical activity intervention design (the “MOVEdiabetes” study) was then developed, implemented and evaluated.

Formative work reported low levels of physical activity and prolonged sitting time in adults with type 2 diabetes. The odds of meeting PA recommendations were significantly greater in males, individuals  $\leq 57$  years, individuals reporting active stages of PA and those with no reported barriers to PA. ‘Lack of willpower’ (in both males and females), ‘Lack of resources’ and ‘Lack of social support’ (more in females) were the most frequently reported barriers.

When participants and health care professionals were asked about acceptable intervention approaches in diabetes primary care, activity consultations were commonly recommended. The perceived actions required to achieve improved activity levels were to modify the current physical structure of the primary health care and provide in-service physical activity training for all health care professions.

A multi-component physical activity “MOVEdiabetes” intervention design was developed for use in a cluster randomised trial. The study was undertaken over a one year period in eight health centres in Muscat. Participants in the intervention group received face to face personalised physical activity consultations on three occasions (0, 4 and 8 weeks), pedometers and monthly WhatsApp messages. The intervention included self-monitoring and feedback

on step counts which was provided within physical activity consultations and discussed through WhatsApp communications whereas the comparison group received usual care. These visits also allowed for data collection by clinic staff for research purposes in all health centres at baseline, 3 and 12 months.

Overall, out of 232 consented participants (122 in the intervention group vs 110 in the comparison group), 174 (75%) completed the final 12 month measurements (82 in the intervention group vs 92 in the comparison group). Results showed significant differences in change in physical activity levels at 12 months from baseline in favour of the intervention group [ $+447.4$  (95%CI 150.7 to 744.1) (MET.min/week)]. Additionally, changes in (secondary outcomes) sitting time ( $-1.5$ , 95%CI  $-2.4$  to  $-0.7$  hours/day), step counts ( $+757$ , 95%CI 18.4 to 1531 steps/day), blood pressure ( $-1.8$ , 95%CI  $-3.5$  to  $-0.1$  and  $-1.6$ , 95%CI  $-2.6$  to  $-0.7$  in systolic and diastolic blood pressure mmHg, respectively), and triglycerides ( $-0.3$ , 95%CI  $-0.5$  to  $-0.08$  mmol/L) were all significantly improved in favour of the intervention group. No significant between group differences were observed for changes in the other anthropometric or metabolic outcome measures.

Moreover, participants in the intervention group had significantly greater improvements in perceived general health, mental health, pain and quality of life compared to the comparison group. Using bespoke exit surveys and observation check lists, perceptions from the participants in the intervention group and project officers revealed that the “MOVEdiabetes” intervention was rated as satisfactory, acceptable, appropriate and was delivered with high fidelity.

The “MOVEdiabetes” programme provided culturally specific intervention level evidence which (when combined with existing evidence) has the potential to influence relevant stake holders, to assist in the development and modification of national physical activity policies and the conduct of programmatic physical activity promotional initiatives. However, future research both locally and regionally, could usefully examine overall physical activity behaviour including the challenges of sedentary lifestyles, and acceptable tools for objective measurement of physical behaviours.

## Glossary and Abbreviations

<b>BCT</b>	Behavioural Change Techniques
<b>BMI</b>	Body mass index
<b>CG</b>	Comparison group
<b>CHC</b>	Comparison Health centres
<b>CI</b>	Confidence interval
<b>DALYs</b>	Disability-Adjusted Life-Years
<b>DiRECT</b>	Diabetes Remission Clinical Trial
<b>DLW</b>	Doubly Labelled Water
<b>DM</b>	Diabetes mellitus
<b>DPP</b>	Diabetes Prevention program
<b>DQoI</b>	Diabetes quality of life questionnaire
<b>DSE</b>	Diabetes support and education
<b>EMR</b>	Eastern Medetereanian region
<b>FGD</b>	Focus group discussions
<b>GCC</b>	Gulf Cooperation Council
<b>GLM</b>	Generalised Linear Model
<b>GPAQ</b>	Global physical activity questionnaire
<b>HBM</b>	Health belief model
<b>HDL</b>	High density lipoproteins
<b>HIS</b>	Health Information System



<b>HPs</b>	Health professionals/ health care professionals
<b>IDF</b>	International Diabetes Federation
<b>IG</b>	Intervention group
<b>IHC</b>	Intervention Health centres
<b>ILI</b>	Intensive lifestyle interventions
<b>IPAQ</b>	International Physical Activity Questionnaire
<b>LDL</b>	Low density lipoproteins
<b>NEAT</b>	Non-exercise activity thermogenesis
<b>MENA</b>	Middle East and North Africa region
<b>METs</b>	Metabolic equivalents
<b>MoH</b>	Ministry of Health
<b>OGTT</b>	Oral glucose tolerance tests
<b>OR</b>	Odds ratio
<b>PA</b>	Physical activity
<b>PHC</b>	Primary Health Care
<b>POs</b>	Project Officers
<b>T2D</b>	Type 2 diabetes
<b>TPB</b>	Theory of Planned Behaviour
<b>TTM</b>	Trans-theoretical model
<b>TG</b>	Triglycerides
<b>Scot-PASQ</b>	Scottish Physical Activity Screening Questionnaire
<b>SD</b>	Standard deviation

<b>SDT</b>	Self-determination theory
<b>SE</b>	Standard error
<b>VO2</b>	Oxygen consumption
<b>WHO</b>	World Health Organization

## Chapter 1 : Introduction

### 1.1 Background

In 2017, the International Diabetes Federation (IDF) estimated that 8.8% of the global population aged 20-79 have diabetes (425 million) of which 90% have type 2 diabetes (T2D) (International Diabetes Federation, 2017). In countries of the Middle East and North Africa (MENA) region, it is estimated that the number of people with diabetes will increase by 110% by 2045, which is the second highest regional increase after Africa (156%) (International Diabetes Federation, 2017). The negative impact of diabetes on health care system expenditures, population productivity and quality of life is of great concern.

Physical inactivity is estimated as being the principal cause for 27% of diabetes, and 30% of ischemic heart disease (Guthold et al., 2018). Similarly, greater sitting time is considered an independent risk factor for diabetes, cardiovascular disease, and all-cause mortality (Ekelund et al., 2016, Edwardson et al., 2012, Wilmot et al., 2012b, Hamasaki, 2016). Sitting more than 8h/day leads to increase risk of all-cause mortality even among individuals achieving the recommended 150 min/week of moderate to vigorous physical activity (PA) (Bell et al., 2014a). As such, addressing low levels of activity and sedentary behaviours in diabetes care are required to reverse this trajectory.

Regular PA has consistently been viewed as a cornerstone in diabetes management (Colberg et al., 2016). However, there is a gap in the literature on the best way to translate/implement methods to promote PA within the routine care of adults with diabetes within the local clinical setting. Prior to a full review of the literature, this chapter introduces the essential definitions/concepts that underpin this PhD project namely diabetes mellitus, physical activity, translational research and primary health care (PHC).

## 1.2 Diabetes mellitus

### 1.2.1 Diabetes mellitus

Diabetes mellitus (DM) is a non-communicable metabolic diseases that occurs when the body fails to produce enough insulin (the hormone that allows glucose to enter into the body's cells for energy production) or fails to use endogenous insulin effectively leading to hyperglycaemia (Paul et al., 2004). The resultant hyperglycaemia may cause symptoms of excessive thirst, urination, unusual weight loss, extreme tiredness and blurred vision. There are a number of different types of diabetes: type 1, type 2, gestational diabetes and specific types of diabetes due to other causes such as endocrinopathies (e.g., excess amounts of growth hormone, cortisol, glucagon, epinephrine) and drug induced (American Diabetes Association, 2004). People with type 1 diabetes require insulin therapy to survive, whereas, T2D, can be undiagnosed for years and may only be diagnosed after complications of the disease become symptomatic.

Type 2 diabetes, the focus of this review, accounts for 85% to 95% of all diabetes in high-income countries and may account for an even higher percentage in low- and middle income countries (International Diabetes Federation, 2017, Alhyas et al., 2012). Fasting blood glucose levels, oral glucose tolerance tests (OGTT), or glycated haemoglobin levels (HbA1c) are used to diagnose diabetes. According to the IDF, diabetes mellitus can be diagnosed if one or more of the following criteria are met:

- Fasting plasma glucose  $\geq 7.0$  mmol/L (126 mg/dL) or
- Two-hour plasma glucose  $\geq 11.1$  mmol/L (200 mg/dL) following a 75g oral glucose load or
- A random glucose  $> 11.1$  mmol/L (200 mg/ dL) or
- HbA1c  $\geq 48$  mmol/mol (equivalent to 6.5%).

Diabetes is a long-term disease that requires close monitoring and follow-up by health care providers in order to prevent serious and costly complications

which, if left untreated, can result in significant chronic morbidity and early death. The complications of diabetes are classified as macrovascular (cerebrovascular, ischaemic heart disease or peripheral vascular disease) or microvascular (nephropathy, retinopathy or neuropathy including postural hypotension, abnormal sweating, gastrointestinal problems and erectile dysfunction) (van Dieren et al., 2010, Chaturvedi, 2007). Compared to non-diabetic populations, people with T2D have higher risk of cardiovascular disease which is the leading cause of mortality in this population (Haffner et al., 1998).

Management of diabetes includes achieving euglycaemia and managing symptoms. Furthermore, due to the association of T2D with multiple risk factors targeting a reduction of risk factors to improve health in people with T2D. Such factors include obesity, activity levels, plasma glucose control, blood pressure control, blood lipid control, and reduction of thrombogenicity (Royal College of Physicians., 2008). Hence lifestyle modification (diet and PA) with or without pharmacological input are usually considered essential in routine diabetes care (International Diabetes Federation, 2017).

Recognising the multidimensional nature of the condition, effective diabetes care should be delivered by a multidisciplinary team including trained nurses, health educators, dietitians, pharmacists, and podiatrists at all levels of health service provision: primary, secondary and tertiary (Artola Menéndez et al., 2010, McGill and Felton, 2007, Maislos and Weisman, 2004).

### 1.2.2 Burden of diabetes on health system

Globally, approximately 4.0 million people aged between 20 and 79 years died from diabetes in 2017, which is equivalent to one death every six seconds (International Diabetes Federation, 2017). Close to half (48%) of deaths due to diabetes are in people under the age of 60. The highest number of deaths due to diabetes occurred in countries with the largest numbers of people with the disease (most populated): China, India, USA, and the Russian Federation (van Dieren et al., 2010). IDF estimated around one half of T2D premature mortality to be due to cardiovascular causes and 10% due to renal failure (International

Diabetes Federation, 2017). Furthermore, diabetes causes major complications and organ failure that may lead to societal, economical limitations and disabilities that effect quality of life and ability to work (Breton et al., 2013). It is estimated that the global total health care expenditure for diabetes in 2017 was 727 billion USD (£ 570 billion) and this number is expected to increase to 776 billion if no intervention is taken to fight diabetes (International Diabetes Federation, 2017).

In Oman, approximately, 72.9 per cent of deaths are attributed to NCDs, of which 24.3 percent are due to the cardiovascular diseases and hypertension, seven percent due to cancer and 2.2 percent due to diabetes according to statistics of 2016 (Ministry of Health Oman, 2016a).

Most adults with diabetes are physically inactive (American Diabetes Association, 2010). Work by Ding et al. (2016) on the economic burden of physical inactivity in 142 countries estimated that physical inactivity cost health-care systems international \$ 53.8 billion worldwide in 2013 (\$31.2 billion by the public sector, \$12.9 billion by the private sector, and \$9.7 billion by households). Additionally, physical inactivity related deaths contribute to \$13.7 billion in productivity losses, and physical inactivity was responsible for 13.4 million disability-adjusted life-years (DALYs) worldwide. High-income countries bear a larger proportion of economic burden (80.8% of health-care costs) whereas low-income and middle-income countries have a larger proportion of the disease burden (75.0% of DALYs) (Ding et al., 2016).

### 1.2.3 Causes of type 2 diabetes

Although T2D is a preventable disease, it continues to grow globally due to economic development, the aging population and increasing urbanization, which brings changes in levels of PA and food choice (both in quantity and quality) related to increased availability, marketing and low cost of energy dense foods (Nolan et al., Swinburn et al., 2011). Obesity and physical inactivity are strongly associated with the development of T2D (Badran and Laher, 2012). Being overweight or obese is the fifth leading risk factor for global deaths worldwide and the third in high income countries (World Health Organization.,

2015). Around 3.4 million adults die each year as a result of being overweight or obese (World Health Organization, 2014c, Badran and Laher, 2011).

Ethnicity and genetics are also reported as potential non-modifiable factors in the development of diabetes. Overall, diabetes prevalence is often six times higher for people of South Asian origin and three times higher for those of African origin compared to other nations worldwide (Maruthur., 2013).

#### 1.2.4 Occurrence of diabetes

*Prevalence of diabetes in Middle East and North Africa region (MENA)<sup>1</sup> and Gulf Cooperation Council (GCC)<sup>2</sup> countries*

The IDF has estimated that the MENA region will have a 110% increase in number of people with diabetes by 2045 (International Diabetes Federation, 2017, Zabetian et al., 2013).

Specifically the Arab Gulf countries namely Saudi Arabia (17.7%), and UAE (17.3%) have the highest prevalence of age adjusted comparative diabetes prevalence in MENA region (Badran and Laher, 2012, International Diabetes Federation, 2017). A study by Al-Shookri et al. (2011) presented an increase in prevalence of diabetes in a population of 20-79 year olds in five of the GCC countries (UAE, Saudi Arabia, Kuwait, Bahrain and Oman) from 2003 to 2010 along with the projected prevalence for the year 2030 (Al-Shookri et al., 2011). Although Oman seemed to have the lowest diabetes projections for the year 2030 (15%) compared to the other countries, the reported estimates were still

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<sup>1</sup> The Middle East and North Africa region according to the International Diabetes Federation consist of (Saudi Arabia, Kuwait, Bahrain, Qatar, Lebanon, Egypt, UAE, Tunisia, Libya, Jordan, Iran, Sudan, Syria, Oman, Iraq, Algeria, Morocco, Pakistan, Occupied Palestinian Territory, Yemen and Afghanistan)

<sup>2</sup> The Cooperation Council for the Arab States of the Gulf is a regional intergovernmental political and economic union consisting of all Arab states of the Persian Gulf except Iraq (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates).

above the global projections on diabetes prevalence for 2045 (9.9%) (International Diabetes Federation, 2017).

Two systematic reviews have looked at diabetes in the MENA region and GCC countries (Table 1.1) and have examined the prevalence of diabetes, associated risk factors, complications, mortality, and management (Alhyas et al., 2012, Zabetian et al., 2013). Conclusions drawn from these reviews were similar to the IDF's report of an increasing prevalence of this disease over time in MENA in general and particularly in the GCC countries. They showed a wide variation in diabetes prevalence across the selected studies ranging between 4.3% and 34.9% in the gulf Arab countries. In addition, macrovascular and microvascular complications were observed in 9-12% and 15-54% of the diabetes population, respectively. Due to the limitations of non-comparability of data across the selected studies and lack of data from some countries, the reviews suggested a need for more representative surveillance data to understand the actual burden of diabetes but also encouraged interventions linked to behaviour change towards healthier lifestyle for diabetes prevention and control.



**Table 1.1: Diabetes systematic review articles in MENA region and GCC countries**

Document	Year	Sampling	Findings	Recommendations
Diabetes in the Middle East and North Africa.  (Zabetian et al., 2013)	2013	101 cross-sectional and 9 cohort publications from all the 22 countries of the MENA region published between January 1990 and January 2012.	Diabetes prevalence varied widely across studies, from 2.5% in 1982 to 31.6% in 2011. Older age and higher BMI were the most strongly associated risk factors for diabetes. Among people with diabetes, over half did not meet recommended care targets. Macrovascular and microvascular complications were observed in 9–12% and 15–54% of diabetes population, respectively.	To take actions on design and implementation of diabetes prevention and control programs including: emphasis on self-management and management in primary care/community settings.
Prevalence of type 2 diabetes in the states of the co-operation council for the Arab states of the Gulf.  (Alhyas et al., 2012)	2012	27 studies published between 1982 and 2009. Eleven studies were of Saudi populations, 3 Kuwaiti, 2 Bahraini, 6 Emirati, 4 Omani and 1 Qatari. Sample sizes ranged from 336 to 600132. All were cross-sectional studies.	Prevalence of T2D ranged from 4.3% to 34.9%. The estimated prevalence of T2D were lower in KSA and Oman. The higher rates were seen in Bahrain. Prevalence increased with age (at least to 50–60 years), and that urban residence was associated with higher prevalence. The observed high prevalence of diabetes in the GCC states was likely to be associated with the high prevalence of risk factors for T2D in this region namely physical inactivity, and gestational diabetes and obesity.	Implement strategies for primary prevention to reduce diabetes incidence in the GCC region.  Conduct more studies on prevalence of diabetes in children and in national versus expatriate populations.

### 1.3 The role of physical activity in diabetes aetiology and management

#### 1.3.1 *Definition of physical activity*

Physical activity is defined as any bodily movement produced by skeletal muscles that require energy expenditure (World Health Organization., 2014a). “Exercise” refers to planned or structured PA (Thomas et al., 2006). It involves “repetitive bodily movements performed to improve or maintain one or more of the components of physical fitness: aerobic capacity (or endurance capacity), muscular strength, muscular endurance, flexibility and body composition” (Zanuso et al., 2010). The terms PA and exercise are often used interchangeably in selected articles, both terms have been used in this literature search. Notably, components of PA measurement include frequency, intensity, time and type.

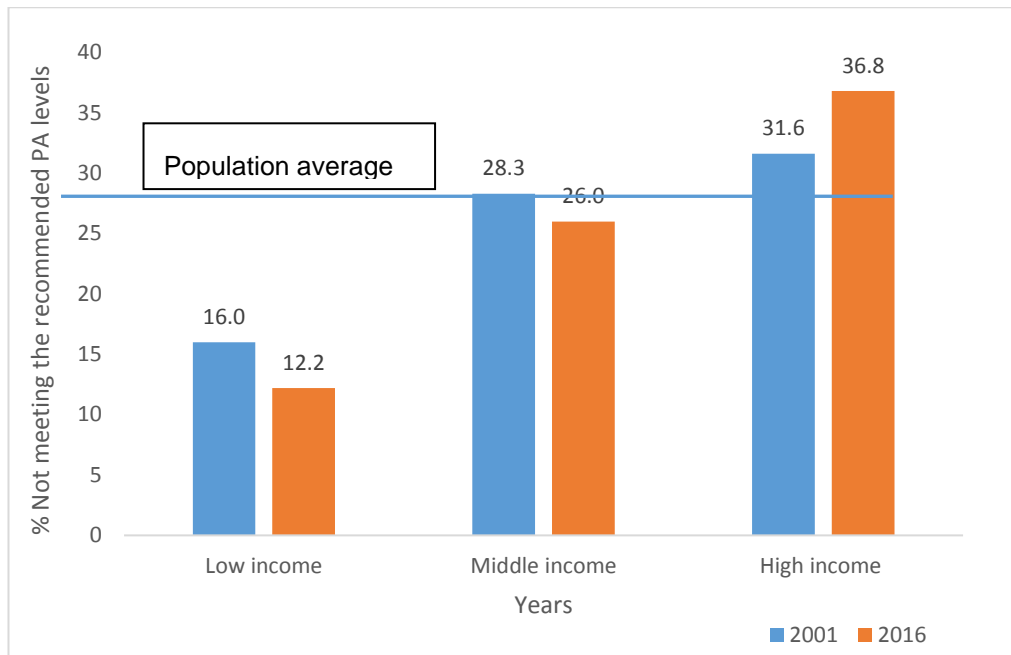
Ranges of PA intensities are quantified by different methods including metabolic equivalents (METs) which is expressed as the ratio of a person's working metabolic rate relative to the resting metabolic rate. One MET is defined as the energy cost of sitting quietly, and is equivalent to an energy consumption of 1 kcal/kg/hour. Light PA is defined as <3.0 METs, moderate as 3.0- < 6.0 METs and vigorous as ≥6.0 METs. On the other hand, Oxygen consumption ( $\text{VO}_2$ ) is another useful way especially when older and younger individuals work at the same absolute MET level but different maximum aerobic capacity.  $\text{VO}_2$  max is defined as the maximum rate at which an individual can consume oxygen during maximum exertion per minute, which realistically increase by age. Hence, 1 MET is equivalent to 3.6ml  $\text{O}_2$ /kg/min (2012, Pate et al., 2008b).

While, sitting time is now recognised as an independent contributor to morbidity (Biswas et al., 2015, van Greevenbroek et al., 2013), it is not the focus of this PhD project. Overall, physical inactivity is estimated as being the principal cause for approximately 27% of diabetes, and approximately 30% of ischemic heart disease (World Health Organization, 2009a, Gupta et al., 2012).

Physical inactivity has also been identified as the fourth leading risk factor for global mortality (6% of deaths globally) after elevated blood glucose levels, tobacco use and high blood pressure (World Health Organization, 2009a). WHO reported that more than 80% of the world's adolescent population does an insufficient amount of PA. Adolescent girls were less active than adolescent boys, with 84% vs. 78% not meeting WHO recommendations (World Health Organization., 2014a). Moreover, worldwide 6-10% of all NCDs can be attributed to physical inactivity, hence it is estimated that increasing PA would increase the life expectancy of the world's population by 0.68 years (range 0.41—0.95) (Lee et al., 2012). People who are physically inactive have a 20% to 30% increased risk of all-cause mortality compared to those who engage in at least 30 minutes of moderate intensity PA most days of the week (Biswas et al., 2015, Lee et al., 2012).

### 1.3.2 Insufficient PA globally

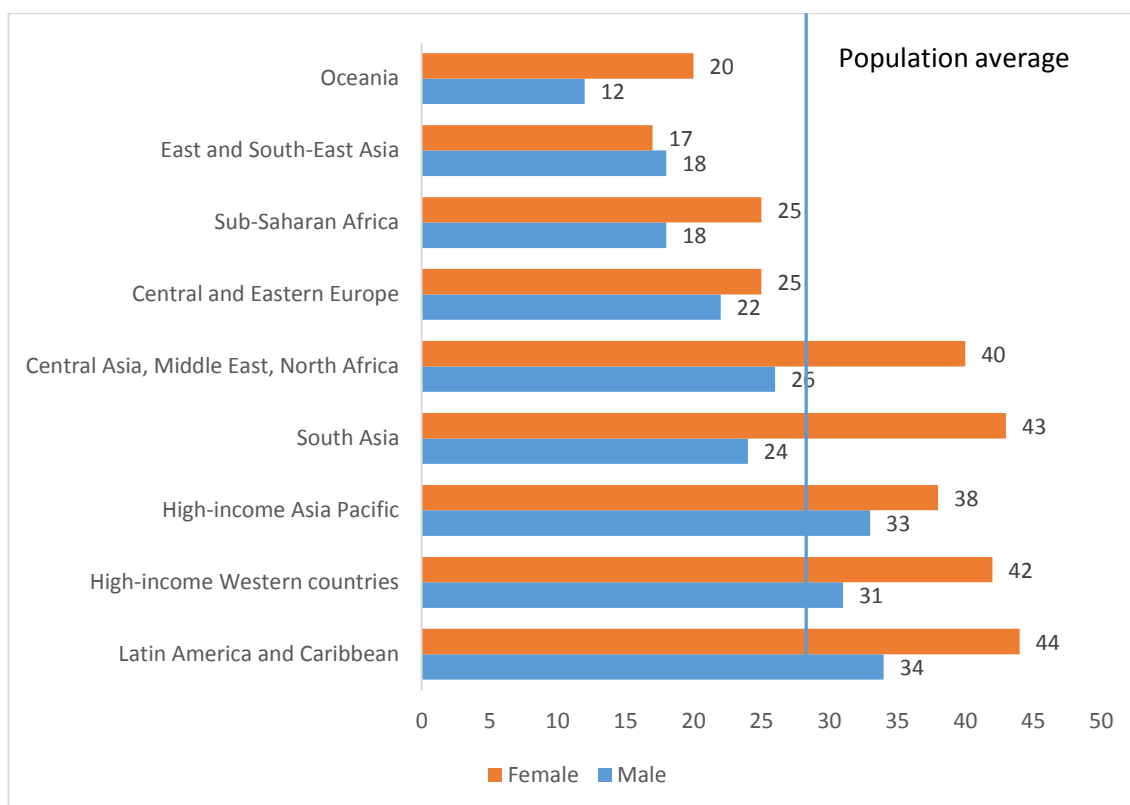
A pooled analysis of 358 population-based WHO surveys from 2001 to 2016 with 1.9 million participants on trends of physical inactivity showed significant findings (Guthold et al., 2018). One in four adults [1.4 billion people worldwide (28% of adults)] do not meet the WHO recommendations on PA to benefit from the reduced risk of common chronic diseases (Guthold et al., 2018). Globally, women are less active (32%) compared with men (23%) and inactivity declines in older age in most countries.



Source: Lancet Global Health, (Guthold et al., 2018)

**Figure 1.1: Levels of physical inactivity in 2001 and 2016 by World Bank Income Group**

The highest levels of physical inactivity in 2016, were in women in Latin America and the Caribbean (43.7%, 42.9–46.5), south Asia (43.0%, 29.6–74.9), and high-income Western countries (42.3%, 39.1–45.4), whereas the lowest levels were in men from Oceania (12.3%, 11.2–17.7), east and southeast Asia (17.6%, 15.7–23.9), and sub-Saharan Africa (17.9%, 15.1–20.5). Prevalence in 2016 was more than twice as high in high-income countries (36.8%, 35.0–38.0) as in low-income countries (16.2%, 14.2–17.9), and insufficient activity has increased in high-income countries over time (31.6%, 27.1–37.2, in 2001) (World Health Organization, 2018a, Guthold et al., 2018) (Figure 1.2).



Source: Lancet Global Health, 2016 (Guthold et al., 2018)

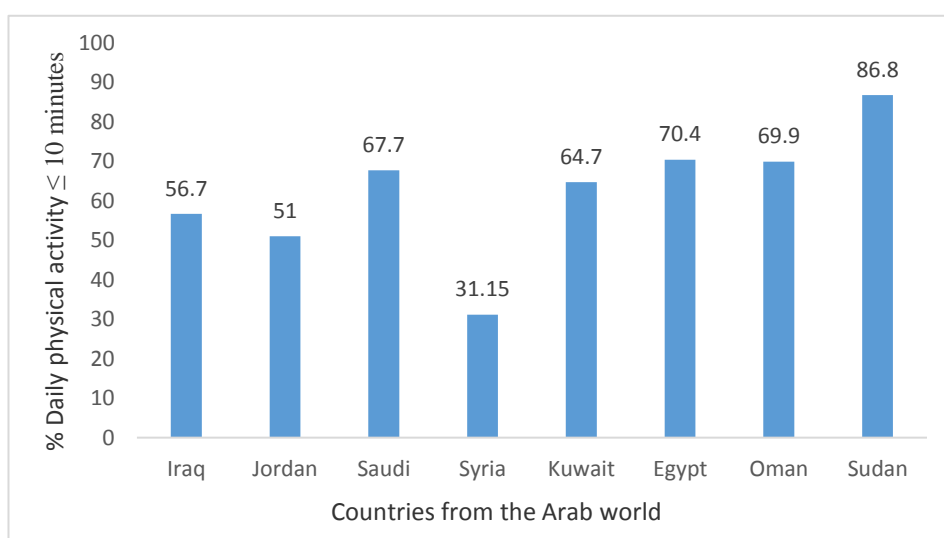
**Figure 1.2: Levels (%) of physical inactivity in 2016 by sex and sub-regions**

Notably, the Global Action Plan on Physical Activity 2018–2030 (World Health Organization, 2018b) provides a shared vision of “More active people for a healthier world” and sets out goals to achieve a relative reduction in global levels of physical inactivity of 10% by 2025 and 15% by 2030. On the 17 October 2018, the WHO launched “ACTIVE, policy toolkit” to help all governments reduce the physical inactivity to reach the proposed goal (World Health Organization, 2018a). The toolkit provides countries with specific policy and interventions to help increase participation levels in PA. Four policy action areas were identified: 1) Active societies, 2) Active environments, 3) Active people, and 4) Active systems.

### 1.3.3 *Physical activity in the Arab World*

Figure 1.2 highlights the high prevalence of physical inactivity in countries of the GCC (Bahrain, Kuwait, Oman, Saudi Arabia, Qatar and UAE) (World Health Organization., 2014b). Using the WHO Global PA Questionnaire (GPAQ), the best estimates for prevalence of PA (percentage reaching PA targets see Section 3.2) in the GCC reported by Mabry et al. (2010a) range from 39.0 to 42.1% for men and 26.3 to 28.4% for women (Mabry et al., 2010a) compared to western populations where it ranges from 50 to 60% for men, and 47 to 54% for women in the USA and Australia, respectively (Bauman et al., 2012a, CDC, 2007).

A review article by Badran and Laher (2012) explored factors contributing to obesity in the Arab world including physical inactivity (daily activity of  $\leq 10$  minutes). Figure 1.3 shows the levels of physical inactivity in selected Arabic speaking countries in which WHO STEPwise survey was conducted from 2003 to 2007. In this dataset, except in Syria, the prevalence of physical inactivity was  $> 50\%$  (Badran and Laher, 2012, World Health Organization, 2005).



Source: (Badran and Laher, 2011)

**Figure 1.3: Prevalence of low PA (daily activity  $\leq 10$  min) in selected countries of the Eastern Mediterranean Region (the WHO STEPwise survey 2003–2007)**

The rapid economic development in the GCC countries has produced significant changes in socioeconomic status and lifestyle; the extensive road networks, increased availability of cars, greater use of mechanized home and farm appliances, widespread use of computers, televisions, and electronic gaming devices have encouraged a more sedentary lifestyle that can lead to greater accumulation of body fat (Rahim et al., 2014, Badran and Laher, 2011).

Extreme outdoor temperatures is a non-modifiable risk factor that creates desertification and a lack of forestation and vegetation in general, forcing people to remain indoors and resort to using cars to travel even relatively short distances (Mabry et al., 2014b). Traditional/cultural restrictions in lifestyle choices available to women in GCC countries may be one explanation for increased rates of physical inactivity in females. Females in the Arab countries have limited access to sporting/exercise activities. This may be accentuated by the easy access to cheap migrant labour for domestic chores. Many families in GCC countries commonly employ cooks and maids adding to a sedentary lifestyle in indigenous women (Mabry et al., 2016, Al-Kandari, 2006, al-Mahroos and al-Roomi, 1999).

#### **1.4 Translational/clinical research**

The application of knowledge from 'theory into practice', is known as translation and is also referred to as 'from bench to bedside' (Pagoto., 2011).

'Theory/bench' interventions are conducted within a controlled research environment whereas 'practice/bedside' are undertaken in a routine care context (Courneya., 2010). Thus, addressing complex behavioural risk factors requires knowledge on the extent to which all intervention components can actually be implemented. This complexity is often attributed to the nature of such interventions in having multi-components at various locations and using multidisciplinary teams to cause a favourable behaviour change. Hence, translation of intervention research evidence becomes essential to ensure that planned interventions can be carried out with equity, are sustainable, and can be replicated elsewhere. Moreover, translational research may have the advantage of using routine health professionals as research staff to implement

the intervention and participants are patients usually representing everyday practice (Courneya., 2010).

Despite the consistent evidence of efficacy of PA interventions in the management of diabetes (Colberg, 2012), very few studies have undertaken PA applicable interventions in Primary Health Care (PHC) and even fewer articles have looked specifically at T2D within a clinical context (Matthews et al., 2014b). Challenges to effective interventions include: funding, time constraints, resources, administration, communication and promotion. Hence, identifying elements for successful implementation of PA under real-world conditions is important to ensure effective clinical practice (Kirk et al., 2004, World Health Organization, 2009a). Moreover, due to cultural, social and clinical differences across different populations, the process of translation of an intervention has to be specific and tailored to everyday variables that cannot be measured in controlled efficacy studies. The range of potential factors present in a natural environment is wide and varied, including: weather, funding, staff knowledge and experience, staff turnover and commitment, venue facilities, transportation, and time constraints (Estabrooks et al., 2011, Colberg et al., 2010a, Weltman et al., 2009). Identifying potential barriers and challenges prior to implementation of an intervention will lead to a successful and sustainable integration of the intervention within routine practice.

Three stages have been described by Dougherty and Conway (2008) to implement translational research including: stage one which is the initial evaluation of a new research finding on human participants, stage two which occurs when findings are incorporated into everyday clinical practice, and stage three is the generalisation of research findings to a wider population (Dougherty and Conway, 2008). Consequently, several translational tools are available to assist researchers and clinicians undertake the process effectively. In this PhD project only the initial stages of translation will be implemented. Elements of process evaluation namely suitability, appropriateness and, fidelity, will be utilised to address the acceptability of the proposed thesis program to patients with T2D and health care providers.



## **1.5 Primary health care**

According to the Alma Ata Declaration in 1978 (World Health Organization Declaration), WHO refers the definition of Primary Health Care (PHC) to the essential health services that are accessible, available, acceptable, and affordable to the public/communities (World Health Organization Declaration). It provides curative, preventive, health promoting, and rehabilitative services. Delivery of services is done by trained physicians, nurses, allied professions such as health educators, dietitians, and others working as a health team and is supported at the local and referral secondary and tertiary care levels.

PHC incorporates a multi-sectoral approach where concerned sectors are equally important in promoting the health of communities. These sectors may include: agriculture, education, housing, municipality and community organizations (governmental and non-governmental voluntary organizations). This approach links the PHC long-lived interventions to people's underlying socioeconomic conditions to address factors that contribute to their poor health. Due to its accessibility and wide services in primary health care, this approach is considered ideal for the management of long-term chronic conditions such as diabetes (Angermayr et al., 2010). Finally, in many countries, PHC is the gate to health care and captures the vast majority of the population, makes it an ideal setting for promoting healthy behaviours/lifestyle.

## **1.6 Summary**

This introduction has provided the initial background to this thesis by introducing Type 2 diabetes, physical activity, translational/applicable research and primary health care. The prevalence of diabetes and physical inactivity is on the rise especially in the GCC countries.

An extensive range of PA interventions in a controlled environment show positive changes in adults with T2D. However, more information is required on how PA interventions work in practical clinical settings.

The PHC has been considered one of the best investment settings for PA promotion. Given the anticipated challenges related to PHCs' structure, staff turnover, and experiences, translational/applicable research is considered useful. Findings from the translational/applicable research are hoped to provide useful information to facilitate adoption and implementation by health professionals and policy makers.

## Chapter 2 : Overview on the context of Oman

### 2.1 Oman – Geography, Population, Development, Health System and Culture

#### 2.1.1 Geography, population and climate

The Sultanate of Oman lies in Southwest Asia on the Southeast coast of the Arabian Peninsula. It is about 309,500km<sup>2</sup>. It is bordered on the north by the United Arab Emirates (U.A.E.), on the Northwest by Saudi Arabia, and on the Southwest by the Republic of Yemen (Figure 2.1). It includes different terrains; sand and desert account for 82% of the total area.

The capital and largest city is Muscat (population size 775,878). There are four other major cities: Salalah (population size 172,570), Nizwa (population size 84,528), Sohar (population size 140,006) and Sur (population size 64,988). The sultanate of Oman is administratively divided into eleven governorates with 61 districts (locally known as wilayat) distributed among the governorates. According to the 2010 census (most recent), the total population of Oman was 2.77 million (~30% non-Omanis). However, current national population estimates in the beginning of 2018 was 4,660,153 with ~45% non-Omani indicating significant growth (or immigration). About 32% of the total population live in Muscat (National Centre For Statistics and Information, 2018).

The climate is hot and humid in summer in the coastal areas, hot and dry in the interior, and some high areas have moderate weather throughout the year. Rain in Oman is scarce and irregular. However, heavy rainfall is also sometimes reported. Governorate of Dhofar is an exception, where heavy and regular monsoon rain is registered from June to October (Ministry of Tourism Oman, 2017).



Source: <http://www.bing.com/images/search?q=maps+of+Oman&id>

**Figure 2.1: Oman map**

### 2.1.2 Development in Oman

Oman's socio-cultural environment is changing rapidly as the country's economic development progresses. The economy of Oman is mainly dependent on crude oil. Commercial export of oil in Oman began in 1967, which was associated with a gradual economic development of the country. The non-oil industrial sectors', such as agriculture, fishing and tourism, contribution to the national economy is expected to increase from 7.5% to 29% by 2020 (Ministry of National Economy Oman, 2016).

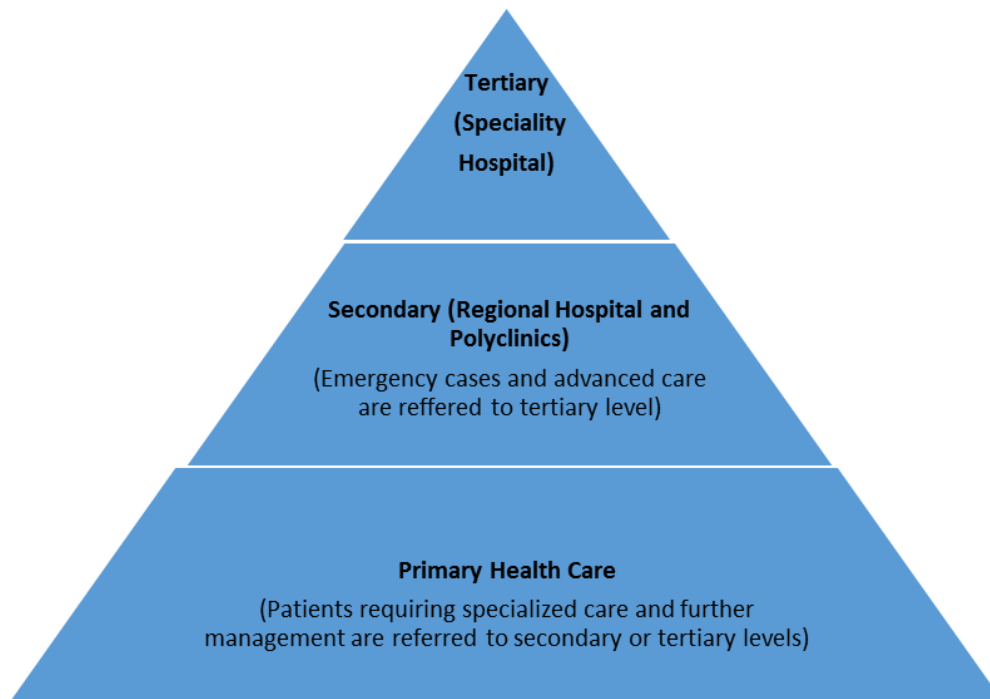
The adult literacy rate (education for less than high school) increased from 81.4% in 2003 to 93.97 % (men 96%, women 90%) in 2015 growing at an average annual rate of 3.69 % (World Data Atlas, 2015). All Omani nationals (men and women) enjoy free education through post-secondary school, vocational and higher education (National Centre For Statistics and Information, 2018).

In spite of the economic success, some challenges remain. For instance, about 25% of Omani households earn  $\leq 500$  Omani Rials a month which is half the monthly mean expenditure of households nationally (Ministry of National Economy Oman, 2016). Furthermore, the employment to population ratio of Oman increased from 44.1 % in 2001 to 57.7 % in 2017, however, a significant portion of the Omani labour force is still seeking employment (~28%) (National Centre For Statistics and Information, 2018).

Due to substantial governmental social support with wide access to basic services to unemployed individuals, poverty levels are difficult to ascertain. In addition to the provision of education and health services free of charge to citizens the government provides direct financial support to the disadvantaged and people below subsistence levels, inclusive of persons with special needs, widowed and divorced women, families of prisoners, orphans and the elderly (National Centre For Statistics and Information, 2018, Ministry of Social Affairs Oman, 2016).

### 2.1.3 Health system

The Ministry of Health (MoH) is the Sultanate's main agency responsible for co-ordination and stewardship of the health sector. The MoH provides health care through its health care delivery institutions at multiple levels, these being integrated through a referral chain and include clinics and hospitals, which are run by other agencies yet linked with the MoH system through referral and feedback system as illustrated in Figure 2.2.



**Figure 2.2: The organizational structure of health system in Oman**

Oman is now recognized internationally as one of the Arabian countries with successful experience in health development. The World Health Organization (WHO), in its first-ever comparative analysis of health systems in 2000, ranked Oman first among 191 WHO member states for its overall performance on the level of health (World Health Report, 2000). It has achieved remarkable success in evolving policies and plans for controlling or eradicating major communicable diseases in the last four decades (Ministry of Health Oman, 2011). These include the expanded program of immunisation, which was initiated in 1981 and the establishment of the disease surveillance and control system in 1987 (Ministry of Health Oman, 2012a). Poliomyelitis has been eradicated and no case of diphtheria has been recorded since 1993 and 1992, respectively. Remarkable achievements have been made in controlling other communicable diseases such as tuberculosis and leprosy. Control of malaria, once a deadly disease in Oman, has been a great success. The neonatal mortality rate is 9.3%, National maternal mortality rate is 13.4% and life expectancy is 76.9 years. However, the country is faced with NCDs associated with lifestyle behaviours.

#### 2.1.4 Culture

The effect of culture on Omani health behaviours and beliefs is important in every aspect of daily life. Islam, the main religion in Oman, is one of the major dimensions of culture and social structure of the Omani community that affects health patterns and practices (Al-Shookri et al., 2011). Tradition, ritual, family structure, food habits, social and geographical elements all influence culture and hence play a significant role on decisions for healthy choices and practices. In Oman there are common food habits related to culture, such as serving dates along with strong non-sweetened coffee. Dates are useful and nutritious (good source of vitamins, minerals and fiber), but the high sugar content makes them unsuitable in larger amounts for people with diabetes. Islamic literature mentions that a healthy diet should be promoted, as well as not eating too much, with emphasis on wholesome food practices (Al-Shookri et al., 2011). Al-Shookri et al. (2011) emphasized that diabetes health care providers must be aware of the impact of culture on patient's behavior, dietary habits and practices before these beliefs and practices can be modified or improved, as these elements play an important role in decision making processes in the patients' everyday life with diabetes (Al-Shookri et al., 2011, Haque et al., 2011).

## 2.2 Diabetes studies in Oman

### 2.2.1 Prevalence and diabetes research in Oman

Diabetes prevalence in Oman increased from 8.3% in 1991 to 11.6% in 2000 and 12.3% in 2008 and recent estimates in 2017 from the Oman Non-Communicable Diseases and Risk Factors Survey (with the collaboration of WHO) are in the order of 15.7% (Oman Ministry of Health, 2017).

A study by Al-Lawati et al. (2015) examined two decades of diabetes research across the Sultanate. Results showed that the age-adjusted prevalence of T2D varied from 10.4% to 21.1%. Higher incidence rates of T2D were found in women vs men (2.7 vs 2.3 cases per 1,000 person-years respectively).

Alarming, T2D has been estimated to increase by 174% in 35 years' time (Al-Lawati et al., 2015).

Five review articles, identified from 2004 onwards, critically analysed the situation of diabetes in Oman (Al-Lawati et al., 2015, Al-Riyami, 2010, Al-Shookri et al., 2011, Ganguly et al., 2009, Al-Lawati et al., 2008). Table 2.1 and Table 2.2 summarizes the main findings reported in these studies (described later) which looked at prevalence, risk factors, management of diabetes and recommendations for diabetes control.

The majority of published articles on diabetes in Oman are descriptive with insufficient data on risk factors, behaviour patterns and status of complications. More importantly, statistics extracted from the computerized Al Shifaa health system have not been formally assessed and reported data may be imprecise (Al-Lawati, 2002).

Al Riyami et al. (2012a) reported diabetes prevalence from the Oman World Health Survey (OWHS) in 2008 as 12.3% of which 64% of patients were poorly controlled with elevated levels of HbA1c. Al-Maskari et al. (2011) on the other hand reported quality of life of patients with type 2 diabetes (T2D) using diabetes quality of life questionnaire (DQoL). The results showed significantly better overall DQoL for patients with less than 5 years of disease duration and HbA1c less than 8% reported. Being aged less than 40 years was significantly associated with better self-care reflected in adherence scores and total score of DQoL (Al-Maskari et al., 2011). To follow on quality of diabetes care, Al Mandhari et al (2009), in a cross-sectional study of six health centres (430 diabetic subjects) in Muscat, evaluated the quality of diabetes care. The study looked at documentation of patients' records, and adherence to diabetes management guidelines. More than 70% of the patients had their blood pressure, fasting or random blood sugar and HbA1C levels measured annually; however, the proportion of those meeting the expected goals of risk factor control was much lower. Only 2.4% achieved the internationally recognised goals for all 6 diabetes related factors (HbA1c <7.0%, BP  $\leq$ 130/80, total cholesterol <5.2mmol/L, LDL <3.3mmol/L, HDL-cholesterol >1.1- <1.68mmol/L and triglycerides <1.8mmol/L). Self-management support to patients,



maintaining disease registries, and monitoring compliance were strongly recommended (Al-Mandhari et al., 2009).

The importance of diabetes education was stressed across the articles (Al-Mandhari et al., 2009, Al Shafae et al., 2008). Additionally, a reform in the current health care system was suggested to include actions to prevent and control non-communicable diseases namely diabetes (Al-Shookri et al., 2011).

In another cross-sectional survey, urbanisation was found to be a significant independent factor for diabetes in Oman (prevalence of diabetes was 17.7% in Muscat compared to 10.5% in rural areas). This could be due to lifestyle, work-related factors and increasing migration of Omanis to the capital city of Muscat in the past 30 years (Al-Moosa et al., 2006, Al-Lawati, 2002).

Qualitative studies by Al-Azri et al. (2011) and Abdulhadi et al. (2007) reported major gaps in the management of patients with diabetes in primary health care such as, lack of continuity of care, shortages of manpower, underutilization of dietitians, inadequate supplies and most importantly suboptimal interaction between primary health care providers and patients with diabetes. Researchers in Oman are still lagging behind in the area of behaviour and lifestyle modifications in diabetes prevention and management and this is corroborated by almost all studies reviewed earlier.

**Table 2.1: Review articles describing the diabetes research in Oman**

Document	Findings	Recommendations
<p>Epidemiology of Diabetes Mellitus in Oman: Results from two decades of research</p> <p>Al-Lawati et al. (2015)</p>	<p>All national surveys conducted between 1991 and 2010 were reviewed. The age-adjusted prevalence of T2D in Oman varied from 10.4% to 21.1%. Higher incidence rates were found in women than men (2.7 vs. 2.3 cases per 1,000 person-years, respectively). No significant trends were observed for the prevalence or incidence of T2D in both genders. Undiagnosed T2D was more common in men (range: 33–68%) than women (range: 27–53%). By 2050, there will be an estimated 350,000, an increase of 174%, people with T2D living in Oman compared to estimates for 2015.</p>	<p>Health authorities need to prioritise diabetes prevention and control in order to prevent or delay long-term complications and avert a potential epidemic of diabetes in Oman</p>
<p>Type 2 Diabetes in Oman: Can we learn from the Lancet editorial (Oman).</p> <p>Al-Riyami (2010)</p>	<p>A narrative review on the increase prevalence of diabetes in Oman. WHO estimates a 190% increase in the number of people living with diabetes in Oman over the next 20 years, from 75,000 in 2000 to 217,000 in 2025. More than 75% of the disease burden in Oman is attributable to non-communicable diseases (NCDs) with the distribution of chronic diseases and related risk factors among the general population being similar to that of industrialized nations; 12% of the population have diabetes, 30% are overweight, 20% are obese, 41% have high cholesterol, and 21% have the metabolic syndrome.</p>	<p>To conduct research on lifestyle interventions to prevent or reverse the complications of diabetes.</p>
<p>Type 2 diabetes in the Sultanate of Oman.</p> <p>Al-Shookri et al. (2011)</p>	<p>A narrative review that explored the increase burden of diabetes in Oman over the last decade, rising from 8.3% in 1991 to 11.6% in 2000 among adults aged 20 years and older.</p>	<p>Reforms are recommended in the current health care system to prevent and control diabetes.</p>

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Epidemiological transition of some diseases in Oman: a situational analysis (Oman).

Ganguly et al. (2009)

Health problems related to un-healthy lifestyle such as obesity, diabetes and hypertension are increasing in Oman.

Lifestyles changes (including eating patterns, smoking habits and regular PA) are recommended in early life.

Addressing the threat of chronic diseases in Oman.

Al-Lawati et al. (2008)

The review examined studies on diabetes in Oman from 1990 through 2005. The socioeconomic indicators were assessed to identify the impact of the changing disease profile on Oman's economy and its health care infrastructure. The elderly population of Oman will increase 6-fold, and the urbanization rate is expected to reach 86%. Chronic diseases will constitute a major drain on Oman's human and financial resources threatening the advances in health and longevity achieved over the past 4 decades.

Implementation of proven, cost-effective primary prevention services that focus on lifestyle and behaviour change.

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**Table 2.2: Studies describing prevalence, risk factors and recommendations for diabetes management in Oman**

Title	Type of study	Population & Sampling	Findings	Recommendations
Oman World Health Survey: Part 1 - methodology, sociodemographic profile and epidemiology of non-communicable diseases in Oman.  Al Riyami et al. (2012b)	OWHS community-based household survey conducted.	Omani and non-Omani population aged 18 years and above  A multi-stage stratified cluster sampling (5000).	For Omanis:  Prevalence of Hypertension (40.3%), Diabetes Mellitus (12.3%- 64% uncontrolled)  Obesity using BMI (24.1%), Total cholesterol (33.6%), Anemia in males 20% and in non-pregnant females was 32.2%.  No data on behaviours patterns was reported.	Develop valid, reliable and comparable information system for adjustment of policies and strategies.
Assessment of quality of life in patients with type 2 diabetes mellitus in Oman.  Al-Maskari et al. (2011)	cross-sectional  diabetes quality of life questionnaire (DQoL)	(200 diabetic clinic)  To measure quality of life of type 2 diabetes patients in Oman, and examine which patients' socio-demographic and diabetes-related clinical characteristics are associated with better quality of life.	Patients with <5 years of disease duration and HbA1c <8% reported significantly better overall quality of life. Patients with ages <40 years have significantly better self-care adherence scores.	Strategies for control of diabetes (glycaemic control) are highly recommended.

Factors affecting the quality of diabetic care in primary care settings in Oman: A qualitative study on patients' perspectives.  Al-Azri et al. (2011)	Qualitative  Face to face interview with 19 Type 2 diabetes patients (patients perspectives)	To explore diabetic patients' views of factors affecting quality of diabetic services delivered in primary care in Oman.	Main factors with negative impact on diabetes care were: delays in the follow-up process; lack of continuity of care; diabetes educational materials unavailable in waiting areas; shortage of Omani nurses able to speak the patients' language; inadequate explanations from the attending primary care physician, under involvement of dietitians in patient management; delays in provision of laboratory results; inadequate supplies of diabetic medication between appointments, and long waits to see ophthalmologists.	Patients' views and concerns in should be considered in order to improve the quality of diabetic care services in primary health care.
Quality of Diabetes Care: A cross sectional observational study in Oman.  Al-Mandhari et al. (2009)	Coss-sectional observational study	430 in 6 health centres	Meeting internationally recognized goals control of diabetes was extremely low.	Patient care management should focus on patient education, training of primary care physicians and other patient care providers in behaviours change.
Knowledge and perceptions of diabetes in a semi-urban Omani population.  Al Shafae et al. (2008)	Questionnaire	563 Omani general public in two semi-urban villages.	The knowledge and preventive measures required to cope with the increasing prevalence of diabetes in Oman seems to be lacking in a significant number of Omanis	Health education could be a powerful tool as they found that level of education is the most significant predictor of desirable knowledge and perceptions of diabetes risk factors, complications and prevention.

Diabetes risk score in Oman: A tool to identify prevalent type 2 diabetes among Arabs of the Middle East.  Al-Lawati and Tuomilehto (2007)	National survey	Oman's 1991 National Diabetes Survey data (n = 4881) to develop a simple diabetes risk score.	Test of the Thai, Dutch, Finnish and Danish diabetes risk scores showed poor performance of these models among Omani Arabs.	Implementation of risk score of Oman to identify individuals at high risk of having T2D in community-based settings in Oman.
Diabetes and urbanization in the Omani population: an analysis of national survey data.  Al-Moosa et al. (2006)	A cross-sectional interviewer-administered survey in Oman including blood and anthropomorphic tests.	7179 individuals aged 20 years or above were interviewed to determine if a more accurate urban and rural categorization would reveal different findings.	Higher prevalence rates of diabetes have been identified in more urbanized areas of the country (18%) relative to more rural areas (11%).	To continue monitoring chronic disease in Oman and to direct public health policy towards preventing an epidemic.
Patient-provider interaction from the perspectives of type 2 diabetes patients in Muscat, Oman.  Abdulhadi et al. (2007)	A qualitative study	90 consultations observed for diabetes management during their consultations with type 2 diabetes patients in six primary health-care centres in the Muscat region, using checklists developed from the National Diabetes Guidelines. Consultations were assessed as optimal or sub-optimal.	50% of the consultations were suboptimal.	Multidisciplinary approach to diabetic care.

### 2.2.2 Burden of DM on health system in Oman

Due to the limitations of the electronic health information system, available data on the burden of diabetes is scarce in Oman. However, it is estimated that health care system and non-communicable disease (NCD) services in Oman are currently dealing with only 50% of people with diabetes and hypertension as stated by Al-Lawati et al. (2008). More than 75% of the disease burden in Oman is attributable to NCDs with the distribution of chronic diseases and related risk factors among the general population being similar to that of industrialized nations; 12% of the population have diabetes, 30% are overweight (BMI >25-29.99), 20% are obese (BMI >30), 41% have high cholesterol, and 21% have the metabolic syndrome (Al Riyami et al., 2012b).

People with diabetes in Oman have high rates of diabetes-related complications. About 50% of patients on renal dialysis and amputation surgeries are due to complications of diabetes. The economic burden of NCDs in Oman has not been researched yet. In addition to QoL of the patients reported by Al-Mandhari et al. (2009), Table 2.3 summarizes some indicators of the burden of NCDs which could indirectly affect the cost of pharmaceuticals, hospitalizations, amputations, dialysis and disabilities attributable to diabetes and other NCD (Al-Lawati, 2002).

**Table 2.3: Some indicators of complications of diabetes from Ministry of Health (2015), Oman**

Indicator	Percentage
Patients keeping their diabetes within control (fasting glucose)	36%
Proportion of patients on dialysis with diabetes	50%
Proportion of diabetes patients with micro-albuminuria	27%
Proportion of amputation surgeries due to complication of diabetes	50%
Proportion of diabetes retinopathy among diabetes patients	14%
Proportion of men and women who have had acute coronary syndrome and have diabetes	33% and 43%, respectively

### 2.2.1 *Diabetes management in Oman*

Since diabetes management was introduced as a priority area in the 5 year health plan in 2003, Arabic-speaking diabetes specialists were recruited to run diabetes clinics throughout the country (Ministry of Health Oman, 2015). However, this role was taken by family physicians on specific days of the week in most primary health care (PHC) centres in Muscat region to provide a specialised care for patients with diabetes. Diabetes management guidelines for PHC are available and practiced across all PHC facilities in Oman (Ministry of Health Oman, 2016a). Additionally, an adult screening program for people 40 years and older (Ministry of Health Oman, 2010) is well established and captures individuals at pre-diabetes stages for early prevention of diabetes.

Diabetes in Oman is managed in a multi-disciplinary team composed of a doctor trained in diabetes management, diabetic nurse, pharmacist, dietitian and health educator. Advice on a healthy lifestyle namely diet and PA, is usually a shared role of the doctor, dietitian and health educator. PA in particular, is frequently a general message rather than tailored to individual patients' needs (Ministry of Health Oman, 2015). Similar to many other developed countries,



very few health-care workers are trained to give appropriate advice about PA in Oman (Peters, 2004).

### 2.2.2 Physical activity in Oman

There is limited information (national, institutional or individual) on the prevalence of physical activity/inactivity in Oman. A narrative review from an unpublished document for the Health System Vision 2050 conference in May 2011 showed that 61% of adults in 2000 were not achieving PA goals and that this number had reduced to 37% in 2008 (Oman Health Vision 2050, 2012). However, these figures are viewed with scepticism given that the prevalence of diabetes has increased from 11.6% in 2000 to 12.3% in 2008. The decrease in physical inactivity may be explained by possibly the subjective nature of collecting data using self-reporting PA questionnaire. Further research maybe needed to confirm these results.

Further work by Mabry et al. (2010a) and (2012) looked at the association of metabolic syndrome with physical inactivity and sitting time in the population of the Sur Healthy Lifestyle Survey (n = 1,335) located in A'Sharqiyah Region. This was reported as the first evidence from the Arabian Gulf Region on associations between PA and sitting time and the metabolic syndrome. The percentage of the sample with the metabolic syndrome (according to the WHO criteria) was 27.3% and was higher in women than in men (29.8% vs 24.2%) with a much greater proportion of women obese compared to men (41.8% vs 21.4%). The trend of higher rates of metabolic syndrome in women is also seen in the Oman population as a whole (40.0% vs 18.4%) as well as in other countries of the GCC (Qatar, 37.7% vs 29.6% and United Arab Emirates, 45.9% vs 32.9%) (Alhyas et al., 2012, GCC statistical center, 2010). The high obesity rates in women may be linked to socio-cultural norms, for example limited gender specific PA facilities that could limit women's options for PA (Ng et al., 2011, Dunstan et al., 2005, Bertrais et al., 2005).

Another study in Sur, Oman, by Mabry et al. (2013) identified socio-demographic, anthropometric and behavioural correlates of work, transport and leisure physical inactivity, and sitting time, among Omani adult men and women aged 20 years and older using a 16-item questionnaire. The population was most inactive in the leisure domain (55.4%), compared to the transport and work domains, similar to some countries in Asia and Africa (Guthold et al., 2011, Abduelkarem and Sackville, 2009, Trinh et al., 2008, Mabry et al., 2010a). All attributes studied showed a significant association with at least one domain of physical inactivity or sitting time and these associations differed significantly by gender. Gender specific correlates of inactivity (in one or more PA domains) were: older age, unemployment, and low fruit and vegetable intake in women; older age, less education, unemployment, marital status of being married and higher BMI in men (Mabry et al., 2013). The study concluded that in the Omani context, the gender variations highlight the importance of understanding the conservative cultural norms that influence how men and women can be physically active.

### 2.2.3 PA policies and guidelines

Five-year health development plans which are set in Oman began in 1976 and are now part of the routine planning, monitoring and evaluation process for the health sector (Ministry of Health Oman, 2011). For example, the 7th Five Year Health Development Plan (2006-2010) included, for the first time, the percentage of adults meeting PA recommendations “walk for 150 minutes per week” as one of the indicators to measure a reduction in chronic disease risk factors (Ministry of Health Oman, 2006 ). On the other hand, integrated action beyond the health sector is a relatively a new approach. The Health Promoting School Initiative introduced in 2004 (Mohamed AJ, 2009) brings together the Ministries of health and education.

In the level of policies, the MoH, in collaboration with other relevant ministries (stakeholders), has developed a national strategy on diet, PA and health (Oman Ministry of Health, 2003). The strategy aims to improve the quality of life by

increasing awareness of what constitutes a healthy lifestyle and reducing the risk factors for non-communicable diseases (i.e. unhealthy diets and physical inactivity). The planning of the strategy's policy and its implementation includes all sectors including civil society, the private sectors and the media. The national strategy is still in the planning phase and hasn't been implemented yet. If successful, it would be the second country in the GCC after Kuwait to develop a national plan addressing physical inactivity (Ramadan et al., 2010). Currently the MoH of Oman is going through a 2050 health system reform and the proposal for PA is integrated within the non-communicable diseases programme. Although the proposal is promising, it is still under study specifically for resources and overall consensus (Oman Health Vision 2050, 2012).

#### 2.2.4 Governmental actions to promote PA in Oman

In Oman, PA intervention studies as such have not been carried out. However, several actions have been taken to promote PA in different governmental sectors. In order to explore these, grey literature, and governmental documents were searched from different PA stakeholders from 2003 onwards specifically from Sultan Qaboos University, MoH, Ministry of Sports Affairs and Muscat Municipality.

##### *Health*

Oman is one of the few countries in the Eastern Mediterranean Region (EMR)<sup>1</sup> that has adapted Community Based Initiatives (CBI) to promote a healthy lifestyle (diet and PA), such as in Sur and Nizwa Healthy Cities, within an administrative structure under the department of CBI in the Ministry of Health

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<sup>1</sup> The World Health Organisations' country grouping includes Bahrain, Cyprus, Iran (Islamic Republic of), Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Oman, Qatar, Saudi Arabia, Syrian Arab Republic, Tunisia, United Arab Emirates, Afghanistan, Djibouti, Egypt, Iraq, Morocco, Pakistan, Somalia, Sudan, and Yemen

(Ministry of Health Oman, 2012b, Al-Siyabi H, 2012). The initiatives are poorly linked to PHC despite multiple stakeholders' involvement (Ministry of Health Oman, 2012b). Moreover, few unpublished short-lived community PA interventions were reported within the annual best national community based initiatives linked to PHC across all regions of Oman. However, reports on implementation, outcomes and sustainability are lacking. Moreover, MoH trained 40 dietitians working in PHC in Muscat region for two days in 2010 on delivering physical education to patients; however the outcome of the training was not well documented and translation of the training to daily practice was not mandated. The trained dietitians were not supervised to implement or deliver any PA education to clients of PHC and thus the impact of this training on populations' PA behaviour cannot be evaluated.

Community Support Groups (CSGs) are interesting allied health groups in Oman who facilitate community health promotional and educational activities including PA. They are an organised group of volunteers who belong to specific catchment areas of PHC centres. Over the years, the role of CSGs in health and specifically in promoting PA is rarely acknowledged and /or appreciated. Despite the existence of a strong PHC administrative framework for CSGs at the level of the communities' namely "willayats", the framework lacks the ability to motivate and authorize the individuals to make relevant PA changes. The framework allows limited and short-term community health educational activities with no significant health impacts. Other more specialised groups do exist (community cancer groups) but their performance in promoting PA is either limited or not significant.

In February 2018, a national action plan for NCD including PA was launched (Oman Ministry of Health, 2018, Mabry et al., 2014a), however a cross-sectoral implementation plan is yet to be developed and executed.

### *Sports and recreation*

Although the theme of the Ministry of Sports Affairs is "sports for all" (Ministry of Sports Affairs Oman, 2011), government facilities lack sporting options besides

football that are accessible for men and women of all ages. Recommendations were documented to promote women-only venues involving other non-governmental and private institutions, such as the Omani Women's Association under the Ministry of Social Development. However, because many adults are neither athletes nor interested in participating in competitive sports, the scope of the Ministry of Sports Affairs is broadened to promote and support informal recreational sports like walking, hiking, biking and swimming. In 2007, the women's aerobics classes was initiated in government sports facilities in the capital area (A Seeb & Bousher) are promising initiatives but they lack trained supervision and linkage to health benefits. The two initiatives have attracted women above 18 years of age for more than 7 years; however intermittent withdrawals and lack of documented health benefits are recognized challenges (Al-Siyabi H, 2012).

### *Workplace*

Promoting PA in the workplace has been consistently recommended in many studies (Anderson et al., 2009), and in Oman, promoting PA is a requirement for private large companies with more than 50 employees (Ministry of Manpower Oman, 2008, Ministry of National Economy Oman, 2016). However, no documented efforts or initiatives are put in place to support PA in workplaces and thus more efforts are needed to enforce healthy workplaces. More importantly, one-third of the formal workforce are women (Ministry of National Economy Oman, 2016), and given that previous evidence has shown the vulnerability of women to physical inactivity, PA initiatives at workplaces is one of the priorities of Ministry of Sports Affairs (Ministry of Sports Affairs Oman, 2011).

## **2.3 Conclusion**

The continuing increase in prevalence of diabetes is a public health problem in Oman threatening the advancements in the national health indicators. Several

diabetes research studies in Oman have reported the importance of healthy lifestyle education in the prevention and management of diabetes. However, intervention studies on promoting a healthy lifestyle are lagging behind and researchers need to be encouraged to consider lifestyle in diabetes care.

Management of diabetes on the other hand, has gone through series of developments in MoH including structured diabetes clinics through a multidisciplinary team of a trained doctor, nurse, dietitian, pharmacist, and health educator. Nonetheless, PA is not a well-structured component in routine diabetes care. National opportunities for PA promotion are accessible across various governmental sectors, however they are limited to policies and guidelines, with lack of implementation plans.

## Chapter 3 : Literature review

### 3.1 Background

This literature review is aimed at assessing the evidence base on promoting PA in the management of T2D in order to inform an intervention design for a randomised control trial (RCT) in clinical practice in PHC in Oman. This search starts with a narrative review performed in a systematic way. The five systematic phases of the Behavioural Epidemiology Framework (BEF) have been adopted to guide the search for evidence on PA in the management of T2D (Sallis et al., 2000). For phases four and five, a systematic review was performed specifically to look for PA interventions in diabetes care. The following topics (based on BEF phases) are represented in the review:

1. The association between T2D and PA.
2. Methods of measuring PA.
3. Barriers and facilitators to PA in adults with T2D.
4. Interventions to promote PA for the management of T2D.
5. Evidence for implementation (translational research) of PA services for the management of adults with T2D within PHC.

The following databases were used for this literature search: Medline, Scopus, Cochrane and Web of Science. In addition, relevant reports were searched for PA interventions in the management of T2D from the WHO, International Diabetes Federation (IDF), and American Diabetes Association (ADA). The search included existing PA recommendations within the global, international and national guidelines for management of diabetes and standards of care (The Scottish Intercollegiate Guidelines Network (SIGN), The National Institute for Health and Care Excellence (NICE), Oman Guidelines for Diabetes Management, National Diabetes Guidelines of United Arab Emirates (UAE) and

Diabetes Clinical Practice Guidelines of Kuwait). References of selected articles were also searched. Global, and national articles from 2000 onwards, written in English or translated to English on PA for adults with T2D were selected. The following MeSH terms were used:

- Diabetes and /or Type 2 diabetes.
- Prevalence and /or diabetes burden.
- Physical activity and /or exercise.
- Management and /or control.
- Measuring physical activity.
- Intervention and /or strategy and /or promotion.
- Primary health care and /or primary care and /or routine care.
- Barriers or inhibitors.
- Facilitators or enhancers.
- Behavioural change or behavioural interventions.

### **3.2 Phase one of BEF: the association between T2D and PA**

#### **3.2.1 Benefits of PA in the management of diabetes**

Evidence has consistently found PA to be effective in the management of diabetes (Yanai et al., 2018, Aune et al., 2015, Thent et al., 2013, Reiner et al., 2013, Plotnikoff, 2006, Warburton et al., 2006, American College of Sports Medicine, 2000). Physical activity of 150 minutes of moderate-vigorous intensity a week has been shown to increase insulin sensitivity, lower blood sugar levels, reduce body fat and improve physical fitness (Dunkley et al., 2014,



Ramachandran and Snehalatha, 2011, American Diabetes Association, 2010, Chiasson, 2007). However, despite the strong evidence on the importance of PA in the management of diabetes, over 60% of patients with diabetes in Western countries don't meet the recommended levels of PA (see Table 3.2) (Sadarangani et al., 2014, Heath et al., 2012, Morrato et al., 2007b) and >70% in Arabic speaking countries (Rahim et al., 2014, Sibai et al., 2013). In addition, studies on sedentary behaviour have interested researchers because of its physiological effects on obesity, cardiovascular disease, T2D, and metabolic syndrome risk factors (Ekelund et al., 2016, Biswas et al., 2015, Solomon and Thyfault, 2013, Hamilton et al., 2007). Remarkably, even with adults who meet PA guidelines, prolonged sitting (screen time and time sitting in automobiles) can increase the premature mortality risk (Mansoubi et al., 2014, Grøntved and Hu, 2011, Wilmot et al., 2011, Dunstan et al., 2010). Hence, breaking up sedentary time is beneficial (Ekelund et al., 2016, Sedentary Behaviour Research Network, 2012, Owen et al., 2010). Although sedentary behaviour is extremely important (see Section 1.3.1), the literature search findings reported here largely focus on leisure time PA.

A meta-analysis of 14 randomized controlled trials by Thomas et al. (2006) assessed the effects of exercise in T2D. The trials were of intervention duration of >8 weeks and with an exercise programme in the intervention group (aerobic fitness or progressive resistance training exercise). Compared with the controls, the exercise interventions significantly improved glycaemic control, by a decrease in HbA1c levels of -0.6% (95% CI -0.9 to -0.3). Further analyses showed a trend towards a more pronounced effect on glycaemic control in the shorter-duration trials due to the higher intensity of exercise, as well as the difficulty of maintaining compliance with exercise regimens in longer-term studies. In this study there was no significant difference between groups in whole body mass, blood pressure or cholesterol levels (Thomas et al., 2006). In contrast to these findings, specific benefits of PA and supervised exercise in T2D on lipid profiles and blood pressure have been reported in several other reviews along with benefits on diabetes-related cardiovascular disease (Koivula et al., 2013, Hayashino et al., 2012). No study has reported adverse effects or

any diabetic complications in the exercise groups (Sanz et al., 2010, Church et al., 2010).

A meta-analysis by Zanuso et al. (2010) comprehensively described role of exercise for the management of T2D. This meta-analysis included randomized controlled trials, and cohort studies presented in three domains: aerobic exercise, resistance exercise, and combined. The study reported that combined exercise training seems to determine significant additional change in HbA1c compared with aerobic and resistance trainings alone (Zanuso et al., 2010).

A recent review by Yanai et al. (2018) and Hamasaki (2016) looked at the association between daily PA and T2D. The reviews highlighted the limited evidence regarding daily PA such as gardening and housework in patients with T2D especially those with physical limitations and multiple comorbidities. The review suggested to investigate the effects of the non-exercise activity thermogenesis (NEAT), defined as the energy expenditure of all physical activities other than volitional sporting-like exercise (Levine et al., 2006), on overall health. Hence, measuring PA from the routine activities throughout the day may be important for elderly patients and/or with chronic diseases including diabetes.

Importantly, a study by Di Loreto et al. (2005) evaluated the long-term impact of different amounts of PA (metabolic equivalents [METs] per hour per week) on T2D (n=179). Subjects were randomized to a PA counselling intervention of at least 30 minutes duration conducted by a physician, followed by a telephone call and then by 15-min sessions every 3 months in the outpatient clinic for a total of seven maintenance visits vs usual care. Subjects were followed for 2 years and divided into six groups based on their increments in METs per hour per week from baseline. Table 3.1 shows the incremental positive effects of PA on biomarkers. Levels of voluntary PA were assessed every 3 months with the Modifiable Activity Questionnaire and fluctuations in energy expenditure were reported. Age, diabetes duration, male-to-female ratio, and baseline levels of energy expenditure through voluntary PA did not differ in the six groups. Significantly more PA was associated with positive health outcomes. In fact,

energy expenditure ranging between 11 and 20 METs/h/week significantly reduced HbA1c, total cholesterol, triglycerides, and blood pressure, with a 2.6% reduction of 10-year coronary heart disease (CHD) risk.

**Table 3.1: Impact of PA counselling to T2D patients on anthropometry, HbA1c, blood pressure, lipid profile and 10 year CHD risk, according to energy expenditure achieved [Di Loreto et al. (2005)]**

	Physical activity (METS per hour per week)					
	0 (n=28)	1-10 (n=27)	11-20 (n=31)	21-30 (n= 27)	31-40 (n =32)	>40 (n =34)
Weight (KG)	+0.8	+0.6	+0.1	-2.2	-3.0	-3.2
Waist(cm)	+1.0	+1.0	-0.9	-3.8	-5.5	-7.1
HbA1c %	+0.03	-0.06	-0.4	-0.9	-1.1	-1.1
BP systolic (mmHg)	-1.8	-1.5	-6.4	-5.5	-6.6	-9.2
BP diastolic (mmHg)	-4.6	-2.4	-2.9	-4.8	-5.3	-7.1
Cholesterol (mmol/l)	-0.1	-0.1	-0.3	-0.3	-0.2	-0.3
LDL-cholesterol (mmol/l)	-0.1	-0.2	-0.1	-0.1	-0.2	-0.2
HDL-cholesterol (mmol/l)	+0.1	+1.1	-0.5	+0.1	+0.3	+0.2
Triglyceride (mmol/l)	+0.1	+0.1	-0.5	-0.6	-0.6	-0.8
10 years CHD risk %	+0.1	-0.3	-2.6	-3.7	-4.8	-4.3

Shaded areas present clinical significant changes from baseline

### 3.2.2 PA recommendations for the general adult population and T2D

Based on the recently launched WHO Global Action Plan for Physical Activity 2018-2030 (World Health Organization, 2018b, World Health Organization, 2014a, World Health Organization, 2010), and American College of Sports Medicine guidelines (ACSM) (Thompson et al., 2013, Colberg et al., 2010a), the general adult population should aim to do at least 150 minutes of moderate-intensity aerobic PA throughout the week or at least 75 minutes of vigorous-intensity aerobic PA throughout the week or an equivalent combination of moderate- and vigorous-intensity activity (Table 3.2). Generally, the PA recommendations for adults with T2D are the same as those for the general adult and older adult population. However, all guidelines state that durations of PA greater than the minimum recommendation will provide additional health benefits. Adults with diabetes should be advised to “perform at least 150 min/week of moderate-intensity aerobic PA (50-70% of maximum heart rate), spread over at least 3 days/week with no more than 2 consecutive days without exercise”. In the absence of contraindications, adults with T2D should be encouraged to perform resistance training at least twice per week (Colberg et al., 2016, Balducci et al., 2014, American Diabetes Association, 2013, World Health Organization, 2010, Klein et al., 2004).

In addition to the PA recommendations highlighted in Table 3.2, “older adults (65+ years), with poor mobility, should perform PA to enhance balance and prevent falls on 3 or more days per week” (Department of health, 2011, World Health Organization, 2010). Notably, “when older adults cannot do the recommended amounts of PA due to health conditions, they should be as physically active as their abilities and conditions allow” (World Health Organization, 2010).

Additionally, a Position Statement from the Exercise and Sport Science Australia, recommends a greater minimum duration of PA for people with T2D of at least 210 minutes of MPA per week, or 125 minutes of VPA and at least two resistance training sessions per week (2-4 sets of 8-10 reps) with no more

than two consecutive days between activities (Hordern et al., 2012, American Diabetes Association, 2010).

**Table 3.2: Global recommendations for physical activity for health in adults aged 18–64**

- 
- a) At least 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate and vigorous-intensity activity.
- 
- b) Aerobic activity should be performed in bouts of at least 10 minutes duration.
- c) For additional health benefits, adults should increase their moderate intensity aerobic physical activity to 300 minutes per week, or engage in 150 minutes of vigorous-intensity aerobic physical activity per week, or an equivalent combination of moderate and vigorous-intensity activity.
- d) Muscle-strengthening activities should be done involving major muscle groups on 2 or more days a week.
- 

Source: (World Health Organization, 2010)

### 3.3 Phase two of BEF: methods of measuring PA

Physical activity is a complex behaviour that can vary in type, intensity, duration, frequency and intermittency (Kowalski et al., 2012). Assessment of PA can be done subjectively (behavioural observation and self-report e.g. questionnaire, diary) or objectively (directly measured; e.g. physiological markers, calorimetry, doubly labelled water and motion sensors) (American College of Sports Medicine, 2000). When selecting appropriate methods for PA assessment it is important to consider validity (how well a method measures what it is designed to measure), reliability (how well a method provides the same results under the same conditions), and practicality of use. A review by Trost and O'Neil (2014) on methods used to objectively measure PA in clinical practice, discussed the trade-off between accuracy and practicality while selecting appropriate PA methods. All measures of PA have fundamental strengths and weaknesses. Hence, selecting one PA measurement method

over the other depends on the patient's circumstances and the resources available to clinicians (Trost and O'Neil, 2014, Reilly et al., 2008). Researchers choose their appropriate method by clarifying the primary and secondary outcomes of the PA assessment and linking it to the practical considerations, such as resources, and the characteristics of the population being studied (Medical Research Council., 2014, National Obesity Observatory., 2012).

Direct observation is one of the earliest methods of PA measurement, but is expensive and time consuming and may not be suitable for use in even moderately large groups. Furthermore, observations are confined to relatively short periods, which may not reflect habitual PA, and people often modify their activity when being observed (Kowalski et al., 2012). The validity and reliability of this technique has improved over the years with advances in technology, including the use of video cameras and digital recording systems. While there are other methods to assess PA from energy expenditure calculated from rates of heat lost (calorimetry) or eliminated heavy isotope concentrations in body water [Doubly Labelled Water (DLW)], these are inconvenient for use in the primary care setting (Kowalski et al., 2012).

Motion sensors, on the other hand, can be used to detect body movement and estimate PA. The preference of one type over the other depends mainly on the purpose of measuring PA (Corder et al., 2007). Pedometers, which measure steps on a single axis, are small, inexpensive and easy to use. These devices could complement the use of the PA self-reporting tools in large scale trials. Pedometers in general provide step counts which then can be used as a proxy for PA (Corder et al., 2007). However, generally pedometers have a restricted data storage capacity, are not sensitive to changes in speed, they underestimate distance, and do not determine the intensity or duration of activity performed (Lubans et al., 2009). Despite the reported limitations and the influence of gait speed on step counts, pedometers are useful supporting tool for walking interventions (Shaw et al., 2011) and are perceived as good for follow up, motivation and monitoring purposes (Fitzsimons et al., 2008, ten Hacken and de Greef, 2008, Bassett et al., 2000, Trost&O'Neil, 2014).

Literature from Japan have promoted pedometers as a motivational tool for achieving the goal of 10,000 steps daily recommended as a proxy for achieving 150 minutes of moderate to vigorous PA/week (Tudor-Locke and Bassett, 2004, Yamanouchi et al., 1995). A systematic review of eight randomized controlled trials and 18 observational studies on effectiveness of pedometer use showed significant increases in PA and significant decreases in BMI and blood pressure (Bravata et al., 2007b).

Accelerometers alternatively, are devices that measure bodily movements in terms of acceleration (Chan et al., 2017). This measurement can then be used to estimate the intensity of PA, and therefore energy expenditure over time. Accelerometers can measure human activity on vertical (uniaxial accelerometers), anterior-posterior and medial-lateral (triaxial accelerometers) planes (Chan et al., 2017, Dowd et al., 2012). Notably, there is no significant difference in the measurement of PA in adults from the uniaxial and triaxial accelerometers and thus either could be used in population studies (Vanhelst et al., 2012).

Although accelerometers are more accurate than pedometers, they are reported to be costly. Nevertheless, these devices are more feasible and participant-friendly compared to other methods (Büsching et al., 2012). They also provide the data necessary to allow researchers to distinguish between sedentary, light, moderate and vigorous PA behaviours as well as between continuous and intermittent activity modes. Limitations of accelerometers include the increased time required to analyse the large amount of data provided, participant burden of wearing the device, failure to provide information about the specific type or context of activities performed (e.g., playing football, going to the gym), and risks of falling in vigorous PA (e.g. while swimming) (Edwardson et al., 2017, Büsching et al., 2012). However, recent recommendations on PA interventions in clinical settings are strongly in favour for use of objective PA measurement tools (Oosterom et al., 2018, Trost and O'Neil, 2014) to compare against reaching the recommended levels of PA (Table 3.2) and measure sedentary behaviour.

### 3.4 Phase three: barriers and facilitators to PA in adults with T2D

#### 3.4.1 *Barriers and facilitators to PA among patients with T2D (see Appendix 3.1)*

Among people with T2D, various barriers were reported across a systematic review by Korkiakangas et al. (2011) and several individual studies. The common barriers were lack of time (Egan et al., 2013, Korkiakangas et al., 2011, Hume et al., 2010, Korkiakangas et al., 2009, Mier et al., 2007, Lawton et al., 2006, Donahue et al., 2006, Thomas et al., 2004) and physical constraints including pain (Labrunée et al., 2012, Wanko et al., 2004). Additionally lack of knowledge about importance of PA and limited facilities were also reported as significant barriers to PA across different cultures (Booth et al., 2013, Mier et al., 2007, Thomas et al., 2004). Being overweight, unsafe neighbourhoods, increasing age, less education and being a smoker increased the odds of reporting a barrier among migrant populations like African Americans, South Asian British and Mexican Americans with different diabetes related risk factors (Mier et al., 2007, Lawton et al., 2006, Wanko et al., 2004). Cultural norms and social expectations were also reported as barriers to PA specifically in South Asian (Pakistani and Indian) British populations (Korkiakangas et al., 2009, Lawton et al., 2006) namely appropriate PA clothing and gender specific facilities. Hence a realistic and culturally sensitive approach was recommended for the kinds of activities patients already do in their everyday lives. For example, walking was the preferred type of activity among the Mexican Americans who have T2D (Mier et al., 2007).

Obese patients with T2D, in Ireland, perceived more barriers primarily due to physical discomfort (23.4%), the perception of exercise being too boring (20.7%) and having limited time available to exercise (20%) (Egan et al., 2013). Other less commonly perceived barriers were being too tired, weather, disliking the gym, being depressed, PA being too expensive, having negative past experiences, being embarrassed about physical appearance, having nobody to



exercise with, transport issues, the roads being too dangerous and a lack of support from family/friends. An interesting finding from the study was the fact that pet ownership was significantly associated with meeting exercise targets. However, no causal relationship was reported and further exploration was recommended (Egan et al., 2013). It is important to note that domestic pets such as dogs may not be part of accepted cultural norms of many countries such as countries of MENA region hence this intervention may not be generalizable to these populations.

Labrunée et al. (2012) studied the barriers to practising a home-based PA training program in obese T2D patients in France. The main barriers to PA practice identified were the perception of a low exercise capacity, a poor tolerance to effort, lack of motivation and the existence of pain associated with PA (see Appendix 3.1). Similarly, views of individuals recently diagnosed with T2D in relation to PA were compared with that of health professionals (HPs) in primary and secondary care (Booth et al., 2013). Similar barriers were reported by both groups. Barriers were divided into six main categories: difficulty changing well-established habits, negative perception of the 'new' or recommended regimen, barriers relating to social circumstances, lack of knowledge and understanding, lack of motivation and barriers relating to the practicalities of making lifestyle changes.

Similar to studies on the general public, facilitators to PA were underreported across the various studies. However, enjoyment from exercise, social relationships related to exercise, encouragement from others, benefits to health, the aim of weight control along with family support and the sense of well-being derived from PA seemed to be prominent motivators to PA (Korkiakangas et al., 2011, Mier et al., 2007).

3.4.2 Specific barriers and facilitators to PA in the general population and in adults with comorbidities in the Arab countries and in Oman (see Appendix 3.2)

A review by Benjamin and Donnelly (2013) identified barriers and facilitators to PA in Arabic adults in the middle east. Reported barriers were cited as: individual (e.g. lack of time and health status), social/cultural/policy (e.g. traditional roles for women, lack of social support, use of housemaids), and the environmental (e.g. hot weather, lack of exercise facilities). Some of the facilitators were: Muslim religion (namely positive religious thoughts about benefits of PA to mind and health), desire to have slimmer bodies, and having good social support systems.

In Kuwait, a study to assess PA using the International Physical Activity Questionnaire (IPAQ) in adults with hypertension and/or T2D who were registered at six family-practice health centres reported that 64.4% of the subjects were not participating in regular exercise and 90.4% were overweight and obese Serour et al. (2007). The main barriers to adherence to exercise were lack of time, co-existing diseases and adverse weather conditions. Cultural factors interfering with adherence to lifestyle measures were traditional Kuwaiti food, which is high in fat and calories, stress, high consumption of fast foods, high frequency of social gatherings, abundance of maids, and excessive use of cars (Serour et al., 2007). In UAE, three studies explored barriers to PA: two qualitative (Ali et al., 2010, Berger and Peerson, 2009) and one cross-sectional study (Al-Kaabi et al., 2009). All studies reported PA levels below recommended levels. The two qualitative studies had similar conclusions despite the variation in the characteristics of target responders: young Emirati college women (Berger and Peerson, 2009) and Emirati national women (aged 20–60 years) at high risk of T2D (Ali et al., 2010). Despite the differences in reported barriers to PA among the college students and the older women, social support seemed to be commended by both groups. Moreover, Al-Kaabi et al. (2009) explored barriers to PA among patients with T2D in Arab communities. Only 25% reported an increase in their PA levels following their diagnosis of

diabetes, and only 3% reported PA levels that met the recommended guidelines. Reported barriers to PA were: disease (e.g. osteoarthritis), lack of time, cultural reasons, family responsibilities, beliefs (e.g. exercise is boring), weather conditions, fear of injury, lack of family support, cost of joining the gym, unavailability of nearby parks, laziness, lack of safe places to walk, exercise making diabetes difficult to control, and self-belief (embarrassed to wear sportswear). It is notable that although the study was mostly conducted during the summer months, the weather was not reported to be a major barrier to PA.

Similar PA behaviours have been reported for adults with T2D in the Kingdom of Saudi Arabia. Three studies: in Al-Ahsa, King Khalid University Hospital (Riyadh) and Al-Hassa showed a high prevalence of physical inactivity predominantly among females. In the study carried out in Al-Ahsa, a reported barrier to PA among the females was a lack of time, but they had less internal barriers (e.g. lack of energy or motivation or self-confidence) compared to males. Males on the other hand reported a lack of motivation as their major barrier (Al-Otaibi, 2013). On the contrary, in Riyadh, the most common barrier to PA was a lack of resources especially among females namely lack of gender specific PA facilities. In addition to that, lack of willpower and social support were both barriers for adherence to PA and a healthy diet (AlQuaiz et al., 2009). Similarly, in Al-Hassa levels of PA varied along the three domains of PA of work-transport-leisure using Global Physical Activity Questionnaire (GPAQ) (Amin et al., 2011). Fifty-two percent of subjects met the minimum recommendations when considering total PA (activity from across the three domains), whilst 21% of the subjects were sufficiently active in leisure-time-related activity with  $\geq 5$  days of any combination of walking, moderate or vigorous-intensity activities. Being female, and/or having a higher educational and occupational status were negative predictors to total and leisure-related PA. In addition, barriers toward leisure-related PA included weather, traditions, lack of facilities and time (Amin et al., 2011).

In Qatar, a qualitative study investigated factors affecting PA in Qatari women. Individual in-depth interviews were conducted with 50 Arabic women. Social

support networks, cultural values, religion, changing socio-demographic and economic conditions, heart disease, and a harsh climate affected the ability of these women to pursue a healthy lifestyle (Donnelly et al., 2012).

In Oman, Mabry et al. (2014b) looked at barriers and solutions to addressing physical inactivity and prolonged sitting in the adult population of Oman through a qualitative study involving semi-structured interviews with ten mid-level public health managers. Barriers for physical inactivity were grouped around four themes: (i) Intrapersonal (lack of motivation, awareness and time); (ii) Social (norms restricting women's participation in outdoor activity, low value of physical activity); (iii) Environment (lack of places to be active, weather); and (iv) Policy (ineffective health communication, limited resources).

It is notable that childcare, household work, cultural beliefs, social isolation, and unsafe neighbourhood environment were leading socio-cultural barriers preventing females from attaining recommended levels of PA. Lack of social support from family, living in extended families, living in rural areas, absence of culturally appropriate facilities, and, in some countries, past experiences of war were the main barriers found for not meeting the recommended PA levels in females (Abbasi, 2014).

In conclusion, there are multiple reported barriers to PA in Arab countries and these vary by individual characteristics, disease condition, age, gender, physical and environmental condition and socio-cultural factors. A summary of the studies included in this part of the review is presented in Appendix 3.2.

However, no similar studies were identified for adult patients with T2D in Oman as this population are more vulnerable to physical inactivity.

### 3.4.3 Barriers to PA promotion in PHC

A qualitative study by Matthews et al. (2014a) explored the views of health professionals on the current and future provision of PA promotion within routine diabetes care. Findings demonstrated that a lack of structure for PA promotion and ineffective behaviour change training made PA promotion within routine

diabetes care challenging. Health professionals struggled to prioritize PA within routine consultations. They were clinically driven to provide PA advice to patients; however, they lacked the skills to elicit significant behaviour change. Five recommendations were presented to improve PA promotion within diabetes care, similar to the recommendations of Kirk et al (2007): 1) “having a key member of staff responsible for PA promotion”, 2) “access to a referral route for PA support”, 3) “inclusion of diabetes-specific information in behaviour change training”, 4) “linking the delivery of PA promotion with clinical outcomes”, and 5) “using ‘champions’ to raise the profile of PA within the health service”.

### **3.5 Phase four: interventions to promote PA for the management of diabetes**

#### **3.5.1 Effects of lifestyle modification on people at high risk of T2D (preventive interventions)**

Persuasive scientific evidence demonstrates that lifestyle modification prevents or delays the occurrence of T2D. According to at least five clinical trials [Da Qing study in China (Ayame, 2005), Finland Diabetes prevention Survey (FDPS) (Lindström et al., 2010, Lindström et al., 2003), Diabetes Prevention Program (DPP) in USA (Diabetes Prevention Program Research Group, 2002), Indian Diabetes Prevention program (IDPP) (Ramachandran et al., 2006), and Kosaka study in Japan (Kosaka et al., 2005)], T2D can be prevented by lifestyle changes in subjects at high risk with indications that weight loss is the primary predictor of reducing the incidence of diabetes. However, despite the importance of preventing diabetes, the focus of this literature search is effects of lifestyle modifications on adults with diabetes.

### 3.5.2 Evidence of management of diabetes through lifestyle modification (diet and exercise)

The best evidence for the effectiveness of lifestyle modification on the management of diabetes has been provided by the multi-centre Look AHEAD project. This randomized controlled trial was similar to the DPP study in design, except that the subjects were overweight or obese persons with T2D (Espeland et al., 2007). Differences between the DPP and Look AHEAD trials are in Table 3.3 (Delahanty and Nathan, 2008). The primary objective of the Look AHEAD study was to examine the long-term effects of lifestyle interventions on cardiovascular morbidity and mortality in 5145 overweight or obese participants with T2D. Despite the lack of effect of the intensive lifestyle intervention program on risk of cardiovascular morbidity and mortality, significant positive effects on weight, waist circumference, physical fitness and HbA1C were noted in patients with T2D (Johnston et al., 2014, Wadden et al., 2012, Unick et al., 2011). In addition to that, the intervention group improved their blood glucose with fewer drugs, saving an estimated \$600 per year per patient. They also reported feeling better with less fear of diabetes related complications such as chronic kidney disease, and vision problems.

Gregg et al. (2012), in the Look AHEAD study, examined the association of a long-term intensive weight-loss intervention (ILI) n=2241 vs diabetes support and education (DSE) n=2262 with the frequency of remission from T2D to pre-diabetes or normo-glycaemia. ILI participants lost significantly more weight and experienced greater fitness than DSE participants at years 1 and 4. The ILI group was significantly more likely to experience remission of diabetes (partial or complete), with a remission prevalence of 11.5% during the first year and 7.3% at year 4, compared with 2.0% for the DSE group at both time-points. In addition to that, continuous and sustained remission was evident with the ILI group (Gregg et al., 2012).

**Table 3.3: Summary of differences between DPP and Look AHEAD**

	Diabetes Prevention program (DPP)	Look AHEAD trial
Weight loss goal	Study goal= 7% of initial wt.  Individual goal= 7% of initial wt.	Study goal= 7% of initial wt.  Individual goal=10% of initial wt.
Activity goal	150 minutes per week.	175 minutes per week.
Intervention format	Individual sessions.	Group plus individual sessions.
Frequency of follow up	16 sessions in the 1st 6 months with minimum of one in-person every 2 months thereafter.	24 sessions in the first 6 months; 18 sessions in months 7-12; minimum of monthly individual sessions years 2-4.
Refresher groups/campaigns	3 times/year after 1st 6 months.	2-3 times/ year in years 2 and beyond.
Supervised activity sessions	2 times/week throughout the trial.	Periodically in refreshers or campaign.
Nutrition intervention	Fat gram counting with addition of calorie counting as needed; self-selected diet.	Calorie counting with inclusion of fat gram counting; portion-controlled.
Meal replacements	Recommended as tool box or campaign strategy.	Recommended as a regular part of the portion controlled diet and campaigns.
Basic tool box strategies (to improve or maintain weight loss or PA)	Used throughout the intervention based on identification of barriers to achieving activity and weight loss goals: problem solving strategies and no cost or low cost reinforces for fulfilling behavioural contracts.	Used in first 6 months for difficulty reaching weight loss and activity goals; problem solving; motivational interviewing and behaviour contracts.
Advanced tool box strategies	Higher cost items used to address barriers to weight loss and activity after 6 months once no cost or low cost options had already been tried.	Used after the 6months if participants did not meet activity goal or lose 5% of initial weight or regained 2% or more from lowest weight; includes use of higher cost items including weight loss medication.

Source: Implications of the Diabetes prevention program and Look AHEAD clinical trials for lifestyle interventions (Delahanty and Nathan, 2008).

Altogether, the findings of the DPP and Look AHEAD trials suggest that a modest 5 to 10% body weight loss is achievable and can result in clinically meaningful outcomes with respect to improvements in glycaemic control and cardiovascular risk factors in T2D.

Partial or complete remission of diabetes is defined as the transition from meeting diabetes criteria to a pre-diabetes or non-diabetic level of glycaemia. The appropriate definition of diabetes remission remains an area of ambiguity and debate (Lean et al., 2018, Buse et al., 2009). The ADA's definition is achievement of glycaemia below the diabetic range in the absence of active pharmacological treatment or surgical therapy. Recent results from the 12 month Primary care-led 'Diabetes Remission Clinical Trial' (DiRECT), which targeted weight management for remission of T2D in a cluster randomised control trial, showed significant diabetes remission in 68 (46%) participants in the intervention group and six (4%) participants in the control group (odds ratio 19.7, 95% CI 7.8–49.8;  $p < 0.0001$ ) (Lean et al., 2018). These results strongly justify a practical target of remission of T2D via lifestyle modifications (diet and PA) in diabetes primary care. However, information on acceptability and long-term maintenance is warranted.

### 3.5.3 *Interventions to promote PA for all*

A review of 100 articles on PA promotional activities revealed different intervention methodologies at schools, workplace, community, and clinical settings (Heath et al., 2012). The studies were further classified into intervention strategies according to different domains. These domains were: 1) campaigns and information approaches, 2) behavioural and social approaches, and 3) environmental and policy approaches (Heath et al., 2012). Overall in order to have an impact on PA behaviour, strong recommendations were made for PA initiatives/approaches to be applied to address the correlates of PA at individual/personal, behavioural, social, environmental, and policy levels.



The International Society for Physical Activity and Health (ISPAH), through its advocacy council GAPA (Global Advocacy for Physical Activity) released the Toronto Charter for PA. The guidance from the Toronto Charter (GAPA & ISPAH, 2011) identifies seven best investments to increase population levels of PA which, if applied at sufficient scale will make a significant contribution to reducing the burden of NCDs: 1) school programs, 2) transport policies and systems, 3) urban design regulations and infrastructure, 4) PA and NCD in primary care, 5) public education 6) community programmes, and 7).sports systems and programs that promote 'sport for all'.

#### 3.5.4 Interventions to promote PA for patients with T2D

General findings from a review by Yanai et al. (2018) and Kavookjian et al. (2007) suggest that PA is better than no exercise at all. Intensive regimens (see Table 3.2), if tolerated by patients, achieved better clinical outcomes than less intensive regimens. Table 3.4 summarizes the review articles on PA interventions in management of T2D.

A number of studies by Avery et al. (2016), (2015a, 2014, 2012) reviewed the methods of delivering behavioural interventions to increase PA in adults with T2D. Behavioural interventions showed statistically significant increases in objective and self-reported PA/exercise including clinically significant improvements in glycaemic control, HbA1c and BMI. Clinically significant improvements in HbA1c were linked to utilizing more behaviour change techniques, interventions underpinned by a theory or model of behaviour change, and durations of  $\geq 6$  months. The most frequently used behaviour change techniques included goal-setting, prompts, self-monitoring, problem solving, social support and relapse prevention (Avery et al., 2012). Moreover, the same authors assessed the acceptability, feasibility and fidelity of the multifaceted PA behavioural change intervention in PHC (The Movement as Medicine for T2D study). The intervention consisted of an online accredited training programme for PHC professionals in the United Kingdom (Avery et al., 2016, Avery et al., 2014). Overall, five behaviour change techniques were found

to be statistically associated with increased PA behaviour in T2D and improving HBA1c (Avery et al., 2015a). The techniques included prompt focus on past success, barrier identification/ problem-solving, use of follow-up prompts, providing information on where and when to perform the behaviour and prompt review of behavioural goals of PA. These models of behaviour change and BCTs will be discussed latter in sections 3.5.5 and 3.5.6

**Table 3.4: Review articles on PA in the management of T2D**

Article	Objective	Number of studies included	Findings
Exercise Therapy for Patients With Type 2 Diabetes: A Narrative Review  (Yanai et al., 2018)	To introduce the common literatures about effects of PA on mortality, cardiovascular events, and metabolic parameters, to encourage understanding of exercise therapy, and then describe how to prescribe exercise therapy for patients with T2D	Narrative review based on findings from two prospective Meta-analyses of 50 and 9 cohort studies.	<p>High-intensity training improves metabolic parameters in patients with pre-diabetes or T2D and low PA is associated with an increased risk of incident T2D.</p> <p>It is useful to include non-exercise activity thermogenesis for diabetic patients who cannot perform volitional sporting-like exercise because of diabetic complication and/or comorbidity. Exercise prescriptions for patients with diabetes, should include: 1) kinds of exercise (aerobic exercise or anaerobic exercise including RT), 2) intensity of exercise (METs), 3) frequency (how many times per week), and 4) duration (how long per day or week).</p>
The effects of high-intensity interval training on glucose regulation and insulin resistance: a meta-analysis  (Jelleyman et al., 2015)	To quantify the effects of high-intensity interval training on markers of glucose regulation and insulin resistance compared with control conditions or continuous training.	Meta-analysis (50 studies)	<p>There was a reduction in insulin resistance, HbA1c (by 0.19%) and body weight (-1.3 kg) following high intensity training compared with both of the other groups.</p> <p>There were no statistically significant differences between groups in other outcomes. However, participants at risk of or with T2D experienced reductions in fasting glucose.</p> <p>Larger randomized controlled trials of longer duration than those included in this meta-analysis are required to confirm these results.</p>

Independent and combined effects of physical activity and body mass index on the development of Type 2 Diabetes - a meta-analysis of 9 prospective cohort	.To examine the independent and combined effects of PA and BMI on the incidence of T2D.	meta-analysis (9 studies)	<p>A total of 11,237 incident T2D cases were recorded. Being overweight or obese (compared with normal weight) and having low PA (compared with high PA) were associated with an increased risk of incident T2D (hazard ratios 2.33, 95 % CI 1.95-2.78; 6.10, 95 % CI: 4.63-8.04, and 1.23, 95 % CI: 1.09-1.39, respectively).</p> <p>Individuals who were both obese and had low PA had 7.4-fold (95 % CI 3.47-15.89) increased risk of T2D compared with normal weight, high physically active participants.</p>
(Cloostermans et al., 2015)			
Successful behavioural strategies to increase physical activity and improve glucose control in adults with Type 2 diabetes	To explore which behaviour change techniques and other intervention features are associated with increased levels of PA and improved HbA1c in adults with T2D	Dataset of 21 behaviour change techniques (17RCT)	Four behaviour change techniques (prompt focus on past success, barrier identification/problem-solving, use of follow-up prompts and provide information on where and when to perform physical activity) had significant associations with increased levels of PA.
(Avery et al., 2015a)			
Can physical activity interventions for adults with type 2 diabetes be translated into practice settings? A systematic review using the RE-AIM framework	To report the findings of PA studies within routine diabetes care using RE-AIM (Reach, Effectiveness, Adoption, Implementation and/or Maintenance) framework	12 studies	Tailoring recruitment, resources and intervention delivery to the target population played a positive role in increasing PA level, in addition to the use of external organisations and staff training. Many interventions were of short duration and lacked long-term follow-up data. Findings revealed limited and inconsistent reporting of useful process data.
(Matthews et al., 2014b)			

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<p>The use of technology to promote physical activity in Type 2 diabetes management</p> <p>(Connelly et al., 2013)</p>	<p>To assess the effectiveness of technology to promote PA in people with T2D</p>	<p>15 articles</p>	<p>Technology-based interventions are effective in promoting PA; using further methods to promote participant adherence is associated with greater benefit. Further research should look into strategies to enhance adherence and sustainability in order to increase the effectiveness of technology-based PA intervention in diabetes care.</p>
<p>Community-based physical activity interventions for treatment of type 2 diabetes: a systematic review with meta-analysis</p> <p>(Plotnikoff et al., 2013)</p>	<p>To assess the effectiveness of community-based PA interventions for the treatment of T2D in adult populations</p>	<p>22 (16-RCT, 1-prospective 1-cohort, 1-pretest posttest design, 3-Non-randomized one group before and after design)</p> <p>11 included in the meta-analysis</p>	<p>Meta-analysis revealed a lowering of HbA1c levels by -0.32% (<math>p &lt; 0.06</math>). The findings can guide future PA community-based interventions in adult populations diagnosed with T2D.</p>
<p>Changing physical activity behaviour in type 2 diabetes: a systematic review and meta-analysis of behavioural interventions</p> <p>(Avery et al., 2012)</p>	<p>To establish the effect of behavioural interventions (compared with usual care) on free-living PA/exercise, HbA1c, and BMI in adults with T2D</p>	<p>17 RCTs</p>	<p>Behavioural interventions increased free-living PA/exercise and produced clinically significant improvements in long-term glucose control (Table 2.10).</p>

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<p>Evidence-based intervention in physical activity: lessons from around the world</p> <p>(Heath et al., 2012)</p>	<p>Review of reviews.</p> <p>To identify effective, promising, or emerging PA promotional interventions from around the world</p>	<p>100 (76 narrative; 5 reviews of reviews; 19 meta-analyses)</p>	<p>Many approaches lead to acceptable increases in PA among people of various ages, and from different social groups, countries, and communities.</p>
<p>Physical activity advice only or structured exercise training and association with HbA1c levels in type 2 diabetes: a systematic review and meta-analysis</p> <p>(Umpierre et al., 2011)</p>	<p>To assess associations of structured exercise training regimens (aerobic, resistance, or both) and PA advice with or without dietary cointervention on change in hemoglobin A(1c) (HbA(1c)) in type 2 diabetes patients</p>	<p>47 RCTs</p>	<p>Structured exercise training that consists of aerobic exercise, resistance training, or both combined is associated with HbA1c reduction in patients with T2D. Structured exercise training of more than 150 minutes per week is associated with greater HbA1c declines than that of 150 minutes or less per week. PA advice is associated with lower HbA1c, but only when combined with dietary advice.</p>
<p>Web-based interventions for the management of type 2 diabetes mellitus</p> <p>(Ramadas et al., 2011)</p>	<p>To describe web-based behavioural interventions for the management of T2D mellitusj</p>	<p>20 articles</p>	<p>The web-based interventions demonstrated some level of favourable outcomes, provided they are further enhanced with proper e-research strategies.</p>
<p>Exercise for the management of type 2 diabetes: a review of the evidence</p> <p>(Zanuso et al., 2010)</p>	<p>To critically review the more relevant evidence on the interrelationships between exercise and metabolic outcomes</p>	<p>34 articles</p>	<p>Combined exercise training seems to determine additional change in HbA1c that can be seen significant if compared with aerobic training alone and resistance training alone.</p>

<p>The healthcare sector's role in the U.S. national physical activity plan</p> <p>(Patrick et al., 2009)</p>	<p>Identify effectiveness of interventions based in healthcare settings and offered by healthcare providers on improving PA behaviours in patients</p>	<p>Narrative</p>	<p>Brief stand-alone counselling by physicians has not been shown to be efficacious, but office-based screening and advice to be active, followed by telephone or community support for PA has proven effective in creating lasting PA behaviour improvement. Healthcare delivery models that optimize the organization of services across clinical and community resources may be very compatible with PA promotion in health care.</p>
<p>Walking: a matter of quantity and quality physical activity for type 2 diabetes management</p> <p>(Johnson et al., 2008)</p>	<p>Discuss the importance of walking speed along with the amount of walk.</p>	<p>Narrative</p>	<p>Walking is an acceptable approach for people with T2D to meet current clinical practice guidelines, but consideration of both the total number of daily steps and the walking speed of a portion of those total daily steps are necessary to gain health benefit.</p>
<p>Interventions for being active among individuals with diabetes: a systematic review of the literature</p> <p>(Kavookjian et al., 2007)</p>	<p>To assess and summarize evidence and gaps in the literature regarding the intervention for being active (exercise) among individuals with diabetes</p>	<p>41 studies</p>	<p>Interventions were effective when tailored to the needs of individual participants and delivered as structured PA training.</p>
<p>Physical activity consultation for people with Type 2 diabetes. Evidence and guidelines</p> <p>(Kirk et al., 2007)</p>	<p>Guidelines on how to conduct a physical activity consultation with people who have T2D and reviews the evidence surrounding the effectiveness of this intervention in this population</p>	<p>71 published reports</p>	<p>The review supports the use of the behaviour change model for understanding PA behaviour in people with T2D. The review outlines a number of modifiable variables associated with PA behaviour change.</p>

Interventions to promote walking: systematic review (Ogilvie et al., 2007)	To assess the effects of interventions to promote walking in individuals and populations	19 randomised controlled trials and 29 non-randomised controlled studies	The most successful interventions could increase walking among targeted participants by up to 30-60 minutes a week on average, at least in the short term. Interventions delivered either at the level of the individual (brief advice, supported use of pedometers, telecommunications) or household (individualised marketing) or through groups, can encourage people to walk more, although the sustainability, generalisability, and clinical benefits of many of these approaches are uncertain.
Using pedometers to increase physical activity and improve health: a systematic review (Bravata et al., 2007b)	To evaluate the association of pedometer use with PA and health outcomes among outpatient adults	26 studies (8 RCTs and 18 observational studies)	Pedometer use significantly increased PA by 2491- 2183 (~26.9%) steps per day in RCTs and observational studies respectively. An important predictor of increased PA was having a step goal such as 10,000 steps per day. When data from all studies were combined, pedometer users significantly decreased body mass index by 0.38, and systolic blood pressure by 3.8 mm Hg. Older age and having a step goal were significant predictors for the decrease in body mass index.
Consultations about changing behaviour (Rollnick et al., 2005)	Discuss the importance of consultations in changing behaviour, disease outcomes and mortality	Narrative	Change was more likely if patients were helped to make decisions for themselves rather than being told what to do and use of a guiding style, which is a simplified form of motivational interviewing, may facilitate such decisions.



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<p>Social support in diabetes: a systematic review of controlled intervention studies</p> <p>(van Dam et al., 2005)</p>	<p>To look for effects of social support interventions on health outcomes in primary and outpatient care for T2D</p>	<p>6 controlled trials</p>	<p>Promising new forms of social support: group consultations (better HbA1c and lifestyle), Internet or telephone-based peer support (improved perceived support, increased physical activity, respectively), and social support groups (improved knowledge and psychosocial functioning). Specific social support interventions affect patient self-care and diabetes outcomes. Only in the group consultations study, diabetes control was protected.</p>
<p>Theoretical perspectives to increase clinical effectiveness of lifestyle modification strategies in diabetes</p> <p>(Peters, 2004)</p>	<p>to identify strategies for effective lifestyle counselling in primary health care</p>	<p>Empirical review</p>	<p>Perceptual congruence, mutual goal setting, readiness to change, and tailored interventions were reported to increase the effectiveness of lifestyle intervention counselling by primary care providers.</p>
<p>Does counselling by clinicians improve physical activity? A summary of the evidence for the U.S. Preventive Services Task Force</p> <p>(Eden et al., 2002)</p>	<p>To determine whether counselling adults in primary care settings improves and maintains PA levels</p>	<p>Eight trials involving 9054 adults</p>	<p>Evidence was inconclusive that primary care setting to increase PA is effective.</p>

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### 3.5.5 Behavioural theories for promoting PA (see Appendix 3.3)

Understanding the principles of behavioural change is essential to prepare for the development and implementation of appropriate policies and interventions (Thompson et al., 2013). The most common behaviour change theories for promoting PA are presented in Appendix 3.3. However the social cognitive theory (SCT), trans-theoretical model (TTM), health belief model (HBM) and self-determination theory (SDT) are described below.

#### *Social cognitive theory (SCT) and self-efficacy*

The SCT is a comprehensive theoretical framework that has been used in understanding, describing and changing exercise behaviour across multiple groups and ages (Annesi et al., 2013, Wilcox et al., 2008, Hallam and Petosa, 2004). It is based on behavioural change through the principle of interchanging elements: environmental (physical, social and cultural), personal (emotional, personality, cognition and biology), and behavioural (past and current achievement). These are dynamic elements that affect each other and interact differently over time.

Self-efficacy is a core concept in SCT where one believes in their capabilities to successfully complete a course of action such as exercise (McAuley and Blissmer, 2000). There are two types of self-efficacy when considering exercise behaviour: task self-efficacy and barriers self-efficacy. The former refers to an individual's believe they can actually do the behaviour, while the latter refers to whether an individual believes they can regularly exercise despite presence of barriers (lack of time and poor weather). Exercise task self-efficacy is measured by asking the confidence of an individual to engage in incrementally challenging activities (e.g. confidence to walk continuously at a brisk pace for 15min, 30min, 45min). On the other hand, exercise barrier self-efficacy is measured by asking the confidence of an individual to do a set of amount of exercise when barriers exist (e.g. time, weather, fatigue).

Outcome expectation is another key concept in SCT. If a specific outcome is valued then behaviour change is more likely to occur. Both self-efficacy and positive outcome expectation are necessary for an individual to adopt and maintain a regular PA program (Williams et al., 2005).

#### *Trans-theoretical model (TTM)*

A meta-analysis of 71 articles supported the use of the trans-theoretical model for PA behaviour change in the general population (Marshall and Biddle, 2001). This model is possibly the most popular behavioural theory for promoting PA behaviour among patients with diabetes (Plotnikoff et al., 2010d, Prochaska and Velicer, 1997). The American College of Sports Medicine position statement on exercise and T2D highlights the use of the TTM for promoting PA in people with T2D (American Diabetes Association, 2010). The TTM includes five stages of change that explains different level of readiness: (1) pre-contemplation (not ready), (2) contemplation (getting ready to be regularly active in the next 6 months), (3) Preparation (ready to be regularly active in the next 30 days), (4) Action (regularly active for <6 month), (5) Maintenance (regularly active for ≥6 months) (Reed et al., 1997, Prochaska et al., 1992). This model allows for the possibility of moving through these stages allowing for several unsuccessful attempts. Ten processes of change are associated with the five stages of TTM that can be categorised into two groups of factors: (a) experiential (consciousness raising, dramatic relief, self-reevaluation, social reevaluation, and social liberation); and (b) behavioural (self-liberation, counterconditioning, and stimulus control, contingency management, and helping relationship). Movement from one stage to the other within TTM is facilitated by patterns in decisional balance and self-efficacy (Nigg et al., 2011). Decisional balance is a relative weighing of the pros and cons of changing exercise behaviour. To progress along the stages of TTM, individuals need to increase the pros along with self-efficacy and decrease the cons. To do so, TTM recommends different approaches and strategies to exercise adoption and maintenance that needs to meet individual's stage of behavioural change.

Use of TTM in the aforementioned studies was limited by a lack of exploration of the other components of the TTM, including processes of change, decisional balance or self-efficacy. Further work by Kirk and colleagues on the same population provided more evidence into the processes of change used by individuals receiving a TTM-based intervention (n=70) (Kirk et al., 2004). The intervention evaluated PA counselling over 12 months in 70 inactive people with T2D. Participants were given standard exercise information and randomly assigned to receive PA counselling in a diabetes outpatient clinic versus routine care (no PA counselling). Consultations were delivered at baseline and 6 months, with phone calls at 1 and 3 months post-consultation. At 12 months, more experimental participants compared to controls were in active stages of behaviour. PA counselling based on TTM was effective for promoting PA over 12 months in people with T2D (Kirk et al., 2004).

More work by Plotnikoff et al. (2010d) in a larger sample (n=1157) explored the role of use of processes of change in the TTM on changes in stage of change. Findings provided greater insight into the use of processes of TTM-based behaviour change. Strategies targeting self-efficacy, decisional balance and experiential processes of change were significantly associated with stage progression for individuals in pre-action stages of change; and the use of behavioural processes of change were more effective for individuals in the action or maintenance stage of change.

The main critique on studies investigating the TTM is that it: a) gives a diagnostic approach from which a treatment plan can be devised, b) indicates a 'soft' outcomes such as moving an individual from 'precontemplation' to 'contemplation' which is not proven valuable, c) provides scientific labels that are difficult to understand (e.g. a 'precontemplator' is 'someone who is not planning on changing'), and d) is likely to lead to effective interventions as there is lack of participants in the pre-contemplation stage of change (West, 2005). Simultaneously, there is lack of evidence on the usefulness of TTM application across populations with cultural and social differences. While other models are not extensively researched, several studies reported inconsistent findings on

the effectiveness of PA interventions grounded to: a) Self-determination theory (SDT) (Teixeira et al., 2012, Silva et al., 2010), b) Theory of Planned Behaviour (TPB) (Hardeman et al., 2011, Kinmonth et al., 2008) et al., 2008), c) .Health belief model (HBM) (Jennifer Gristwood, 2011, Kiviniemi et al., 2007).

#### *Health belief model (HBM)*

The HBM hypothesize that readiness to act is influenced by individuals' beliefs on susceptibility to disease, and perceptions of the benefits. The six constructs of HBM are: (1) perceived susceptibility, (2) perceived severity, (3) perceived benefits, (4) perceived barriers, (5) self-efficacy and (6) cues to action. The constructs suggest the appropriate strategy for motivating individuals to create desired change in PA behaviour (Kiviniemi et al., 2007). More research is suggested to illicit the effectiveness of using HBM in PA interventions (Jennifer Gristwood, 2011).

#### *Self-determination theory (SDT)*

The SDT underpins three primary psychosocial needs that have to be satisfied to create change in PA behaviour: (1) self-determination or autonomy, (2) demonstration of competence or mastery and (3) relatedness or ability to experience meaningful social interactions with others. Motivation is the core of this theory (Silva et al., 2010). Self-determination increases with increase in intrinsic motivation where satisfaction, challenge, or pleasure are the main motive for PA. On the other hand, external motivation (use of rewards) has limited and transient effectiveness to get individuals to start exercising. While SDT is not extensively researched, several studies reported effectiveness of PA interventions grounded to SDT to be inconsistent (Teixeira et al., 2012, Silva et al., 2010).

### 3.5.6 Behaviour change techniques (BCTs)

Behaviour change techniques vary across published articles. Consequently Abraham and Michie et al (2008) compiled a taxonomy of techniques used in lifestyle interventions to support researchers to describe their methods using standard and consistent terminology. This taxonomy was updated in 2013 (Abraham and Michie, 2008, Michie et al., 2011b, Michie et al., 2013), and a more comprehensive framework for facilitating behaviour change has been developed. The behaviour change wheel (BCW), was developed based on three criteria: comprehensiveness, coherence, and a clear link to an overarching model of behaviour. The centre of the proposed BCW is a 'behaviour system' involving three essential conditions: capability, opportunity, and motivation (COM-B). This forms the hub of the BCW around which are the nine intervention functions aimed at addressing deficits in one or more of these conditions; around this are placed seven categories of policy that could enable those interventions to occur. The BCW was used successfully to characterise interventions for tobacco control and reducing obesity (Michie et al., 2011a). However, further research is needed to establish how far the BCW can lead to more efficient design of effective interventions for other behaviours such as PA.

Evidence by Bird et al. (2013) and Olander et al. (2013) supported the concept that different BCTs may be more appropriate for different activities or different populations. They reviewed the effectiveness of some of these BCTs in promoting walking and cycling in the general population. The most frequently used techniques were intention formation and self-monitoring. Alternatively, Avery et al (2012) identified ten applications of BCTs in the diabetes population illustrated in Table 3.5. Further work by Avery et al (2015) on the same dataset distinguished five context-appropriate behaviour change strategies for use during time-constrained consultations, which can be used to support people with T2D to increase their levels of PA and improve their glycaemic control.

**Table 3.5: Behaviour change techniques in the diabetes population by Avery et al (2012) & (2015)**

*Barrier identification/problem-solving (e.g. identifying potential barriers to PA and methods to overcome them).
*Prompt review of behavioural goals (e.g. review whether PA goals were achieved followed by revisions).
*Prompting focus on past success (e.g. identifying previous successful attempts at PA).
*Provide information on where and when to perform physical activity (e.g. tips on places and times to access local PA opportunities).
*Use of follow-up prompts (e.g. telephone calls in place of face-to-face sessions to support maintenance).

Time management (e.g. making time to be active).

Goal setting (e.g. supporting individuals to make specific, measurable, achievable, relevant, and timely PA goals).

Plan social support/social change (e.g. encourage individuals to gain social support from others to help achieve PA related goals).

Providing information on the consequences specific to the individual (e.g. information about the benefits and costs of PA to individuals).

Prompting generalization of a target behaviour (e.g. once PA is performed in one situation, the individual is encouraged to try it in another).

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\* BCT appropriate for patients with diabetes

### 3.5.7 Methods used in physical activity interventions in the management of T2D

For this section of the literature search, Medline (n= 406), Scopus (n= 1840) and Web of science (n= 992) were used to identify peer reviewed articles following the keywords of:

- Type 2 diabetes OR T2D AND
- Physical activity OR exercise AND

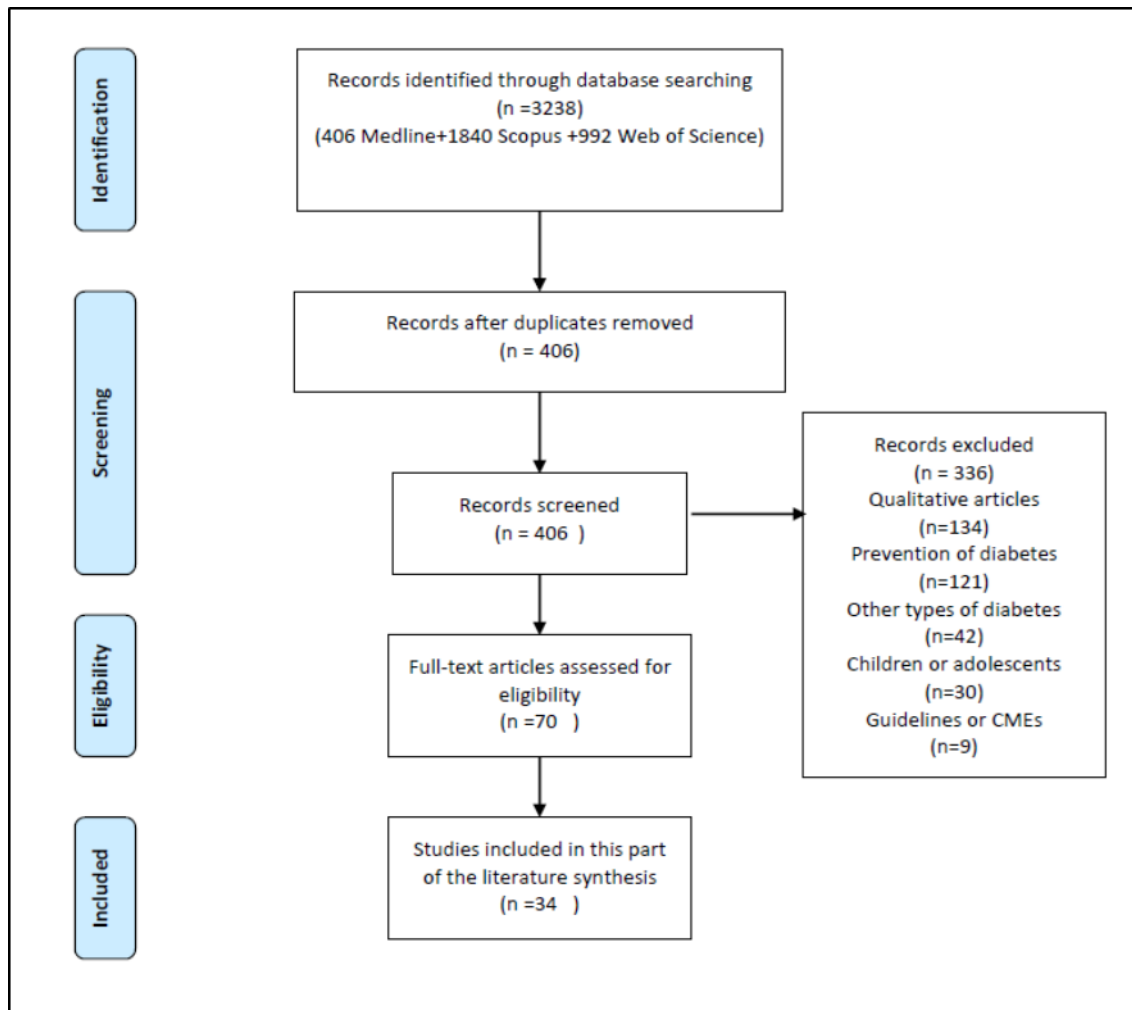
- Strategies OR interventions

Given the high prevalence of diabetes across all age groups (International Diabetes Federation, 2017), the inclusion criteria were interventions involving adults of 18 years or over, with T2D and PA as a component in the outcome measurements. Interventions of PA alone, in combination with diet, or as part of self-management were also included. Exclusion criteria were PA interventions for prevention of diabetes, interventions for children or adolescents and where PA was not an outcome measure.

Figure 3.1 summarises the review process where out of 70 fully reviewed articles, 34 were included in the systematic review.

Overall, the majority of PA promotional interventions for patients with T2D were of short duration (3-6 months), and multiple overlapping PA methods.

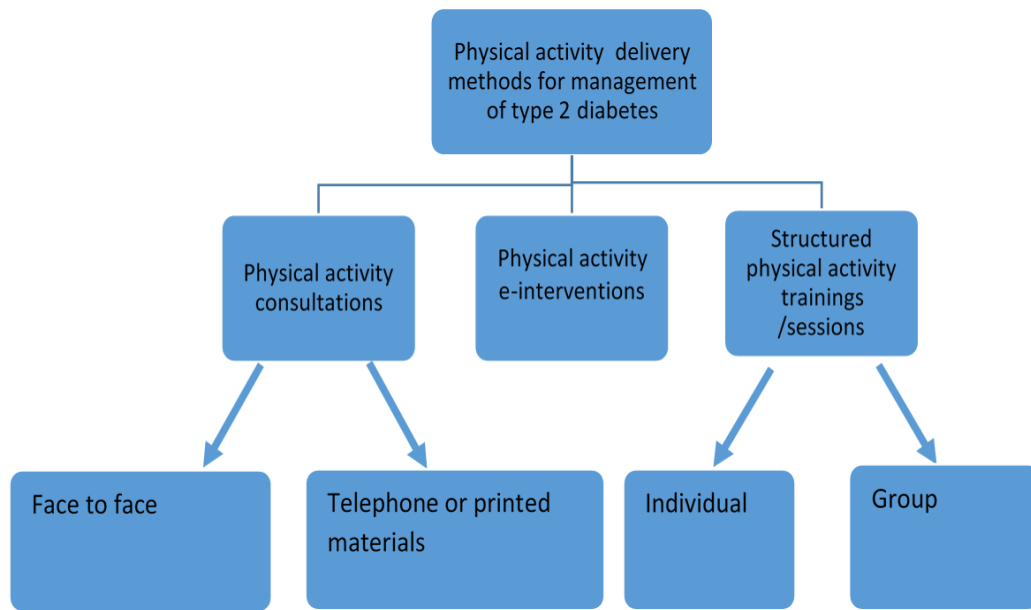




**Figure 3.1: Illustration on the search method for PA interventions for adults with type 2 diabetes**

Due to the overlapping nature of the PA methods used across the various studies, and to facilitate understanding, PA methods were divided into three categories: PA consultations, structured PA sessions and technology based interventions (e-interventions) as demonstrated in Figure 3.2.

It should be noted that none of the studies identified through the literature search were from **Arabic speaking countries** (where diabetes is highly prevalent). Hence, findings of the studies included in this literature search may not be generalizable across different cultures in view of the socio-ecological differences across countries.



**Figure 3.2: Explanatory categories of PA delivery methods in the management of T2D**

### *PA consultation*

Physical activity consultation is ideally a patient centred approach to promote healthy behaviours based on close guidance and tailoring to individual's needs. Elements of the consultation are typically guided to BCTs (Verwey et al., 2016, Avery et al., 2016, Rollnick et al., 2005). Guidelines, published by organisations such as SIGN (Scottish Intercollegiate Guidelines Network, 2010), recommend the use of PA consultation as an effective method for behaviour change in people with diabetes. Positive findings of interventions using PA consultation report successful integration of these consultations within routine diabetes care (Avery et al., 2016, Balducci et al., 2014, Plotnikoff et al., 2011b, Zanuso et al., 2010, Balducci et al., 2009, Balducci et al., 2008, Jackson et al., 2007, Kirk et al., 2007, Di Loreto et al., 2005, Di Loreto et al., 2003). However, the majority of studies are of short duration ( $\leq 3$  months) and long-term follow-up strategies are

often a challenge. Additionally, delivery of PA consultation, face-to-face with participants, can be intensive and time-consuming (Napolitano et al., 2002).

Motivational interviewing (MI) is composed of methods that counsellors use to guide conversations toward behavior change. In MI, there are four processes that help facilitate behavior change: A) “Engagement” (both the counsellor and client establish a helpful connection and working relationship); B) “Focusing” (the counsellor maintains the conversation in a specific direction); C) “Evoking” (helps to elicit the client’s own motivation for change); and D) “Planning” (this requires a commitment for change along with a specific plan of action) (Rollnick et al., 2008). The spirit of MI requires partnership between the counsellor and their patients, to connect behaviour change with each patient’s own values and concerns, and ultimately to respect autonomy by accepting the choices patients make about their lives (Soderlund, 2017).

Provider-based (physicians) PA counselling has undergone systematic review, and more evidence is required to allow its recommendation as a single component intervention (Eden et al., 2002). However, it has promising results when integrated into existing community efforts (Patrick et al., 2009). Additionally, brief stand-alone counselling by providers was reported to be ineffective, but office-based screening and advice followed by telephone or community support for PA does sustain long-term improvements in PA behaviour in patients (van Sluijs et al., 2005) suggesting the need for multiple intervention methods and support for PA behaviour change.

Telephone counselling has had mixed results in terms of its efficacy in adults with T2D (Johnson et al., 2012, Lawler et al., 2010, Plotnikoff et al., 2010a, Eakin et al., 2008, Di Loreto et al., 2003). A RCT by Di Loreto have reported a significant increase in levels of PA at 2-year follow-up (Di Loreto et al., 2003). On the contrary, significant between group differences were found for women only in the study by Plotnikoff et al (2010) on the Alberta Diabetes and Physical Activity Trial (ADAPT). However, no significant between-group differences (group 1/control: standard printed PA educational materials; group 2: as in group 1 plus pedometers, a log book and personalised printed PA information;

group 3: a PA telephone counselling protocol, in addition to the materials provided in groups 1 and 2 (Plotnikoff et al., 2010a).

Further research on the use of peer-counsellors to deliver telephone interventions was found to be a feasible and effective method of PA promotion for people with T2D (Plotnikoff et al., 2010b). The use of peer counsellors has potential for cost-effective delivery of PA promotion within the diabetes population and would benefit from further study.

The Living Well with Diabetes study by Eakin et al. (2013) is a study that explored the significance of telephone delivery in PA promotion. It addressed the gaps in the telephone counselling literature by delivering an 18-month weight loss intervention aimed at promoting maintenance of PA behaviour change. It provided an ambitious protocol to promote 210-mins of moderate PA per week which is higher than the current recommendation of 150-mins per week (Eakin et al., 2010). After 6 and 24 months (Eakin et al., 2014) follow up, the telephone counselling participants achieved modest, but significant, improvements in weight loss, MVPA, and waist circumference, but not in HbA1c level, or other cardio-metabolic markers. None of the outcomes showed a significant change/deterioration over the maintenance period. However, only the intervention effect for MVPA remained statistically significant at 24 months.

#### *Structured PA/ exercise sessions*

A meta-analysis of 47 RCTs by Umpierre et al. (2011) found that structured exercise training that consisted of aerobic exercise, resistance training, or both combined was associated with HbA1c reduction in patients with T2D (−0.73%, −0.57%, and −0.51% respectively). Structured exercise training of more than 150 minutes per week was associated with greater HbA1c declines than that of 150 minutes or less per week. PA advice was associated with lower HbA1c, but only when combined with dietary advice. Nonetheless, comparisons of the interventions in the selected studies in this meta-analysis were reported as difficult due to variations in PA delivery methods. In addition to that, theory-based versus non-theory-based interventions, group versus individual delivery

of information, and delivery within various settings are all confounding factors that adds to the variation in PA interventions.

The role of a structured PA training approach was further supported by the Italian Diabetes Exercise Study (IDES) (Balducci et al., 2008). Results at 12-months found that supervised PA, in combination with PA consultation, was more effective than PA consultation alone in promoting levels of PA, reducing HbA1c and improving cardiovascular risk profile (Balducci et al., 2009).

Interestingly, a study comparing prescribed PA training in a supervised versus unsupervised setting reported no significant difference between the two groups at 2-month follow-up on muscular strength or exercise capacity (Taylor et al., 2009). Several limitations were reported in this study, such as the small sample size (n=24), short follow-up duration, and lack of additional measures to assess total levels of PA. Additionally, a major limitation of PA training is that methods seldom report the use of theory-based behaviour change strategies, potentially limiting its effectiveness due to non-employment of standard behaviour change techniques (see Section 3.5.6). Furthermore, maintenance strategies for participants following the end of the programme are missed in many studies. This information would have provided positive insights for development of maintenance strategies for future interventions sustainability.

Walking interventions combined with the use of pedometers as motivational tools have shown significant results in adults with T2D (Hamasaki, 2016, Funk and Taylor, 2013, Ogilvie et al., 2007). Pedometers have been identified as one of the most effective methods for short-term PA promotion (Matthews et al., 2014b, Heath et al., 2012, Furber et al., 2008, Tudor-Locke et al., 2004, Tudor-Locke et al., 2001). Long-term PA behaviour was also induced by pedometer use in other studies (De Greef et al., 2011, De Greef et al., 2010). Evidence particularly supports the use of pedometers in the promotion of walking activities by 2000-2500 steps per day and they have the advantage of being user-friendly and cost-effective (Alhyas et al., 2012, Bravata et al., 2007b). Notably, pedometer use is linked to many behaviour change strategies, such as: building confidence (improving confidence in walking ability), goal-setting

(individuals may set achievable daily step goals), self-monitoring (recording daily steps in a step-diary), problem-solving (adapting walking behaviour to suit weather and setting), social support (from friends and/or family), and motivation (providing instant feedback to individuals) (Chan et al., 2008, Bravata et al., 2007b). Consistently, walking programmes were observed to be effective if they, a) targeted sedentary individuals or those motivated to change, b) were tailored to the needs of the individual, and c) were delivered via group-based, individual or household approaches. Hence, walking can be considered as an appropriate method of PA promotion for adults with T2D as they are often sedentary individuals, aware of their need for lifestyle change, and in need of tailored information and social support from peers, family or friends (Wen et al., 2014, Ogilvie et al., 2007).

However, while walking interventions have been shown to be effective in increasing step counts in people with T2D, there is a lack of evidence to show that improvements in long-term health outcomes are achieved. Some research suggests that although people with T2D may successfully achieve the current PA guidelines, the intensity of activity may be insufficient to gain measurable health benefits (Hamasaki, 2016, Johnson et al., 2008, Araiza et al., 2006, Johnson et al., 2006). To address this issue Tudor-Locke (2009) attempted to increase the walking speed of participants who had previously completed the First Step Program (Tudor-Locke, 2009, Tudor-Locke et al., 2004, Tudor-Locke et al., 2001). Increased walking intensity or short bouts of running was shown to result in greater improvements in health outcomes in people with T2D who were already walking ~10,000 steps per day (Lee et al., 2014, Di Loreto et al., 2005).

Many pedometer-based studies in the diabetes population are based on a group-setting approach in the delivery of the interventions. Specifically, the study by De Greef et al. (2011) was one of the very few studies that compared a group-based approach with individual counselling in Belgium. The findings suggested that participants in the group-intervention increased their daily steps significantly more than the individual counselling group. Other advantages of group based initiatives include opportunities for sharing of experiences and

knowledge, use of problem-solving skills within group members and reduced burden on staff and resources (Bastiaens et al., 2009, Feathers et al., 2007, van Dam et al., 2005). However, management of logistics (organization, administration, and time allocation) in group settings may be challenging as it requires agreement from all group members (De Greef et al., 2011).

### *Technology-based interventions (e-interventions)*

Technology-based interventions to promote PA have been shown to be effective in people with T2D (Connelly et al., 2013). In a review of 15 studies: web-based (9), mobile phone (3), CD-ROM (2) and computer based (1) interventions were reported to increase PA outcomes, but only nine were significant. Interventions lasted between 6 weeks and 1 year, with four having a follow-up period of between 6 and 18 months. The use of reinforcement strategies such as phone calls and email counselling were found to be effective components for behaviour change. However, almost half of the studies did not assess glycaemic control, making it difficult to associate the impact of the intervention and PA with diabetes outcomes. A recommendation from this article was to have a post-study follow-up to provide evidence for sustainability of positive behaviour (Connelly et al., 2013).

In another review, twenty web-based interventions demonstrated some level of favourable outcomes. Goal-setting, personalized coaching, interactive feedback and online peer support groups were some of the successful approaches within e-interventions (e.g. web-based education and online peer support) (Ramadas et al., 2011). Similar findings were reported in a RCT of more than 300 participants who were randomized to either a computer-assisted, tailored self-management PA intervention (N = 174) or health risk appraisal (N = 161). The computer-assisted, multifaceted approach to PA demonstrated improvements in patterns of PA after 2 months. Participants in the intervention group were capable of adjusting their activity patterns and maximising their PA (King et al., 2006). For participants who completed the 2-month follow-up, the intervention significantly improved PA patterns relative to controls. Nonetheless, the study

was of short duration and further studies were recommended to assess sustainability.

### **3.6 Phase five: evidence for implementation (translational research) of PA services for the management of adults with T2D within PHC**

There is currently no consensus on the optimal method of delivery for PA interventions within routine diabetes care, however, multi-component interventions, including provider advice, supported with behavioural interventions (linked to the community) to facilitate and reinforce healthy levels of PA appear to be “most promising” for those diagnosed with T2D (Avery et al., 2015b, Matthews L., 2013, Eakin et al., 2010, Glasgow et al., 2001). Evidence, largely from developed countries, demonstrates the effectiveness of promoting PA in primary care (Cobiac et al., 2009, Marcus et al., 2006, Eakin et al., 2004). It is also identified as one of seven best investments for PA by the Global Advocacy for PA (GAPA & ISPAH, 2011). A potential benefit of the primary care setting is that participants of the program establish relationships with providers, which may enhance intervention efficacy and implementation as well as minimise attrition. In addition, primary care settings can also manage co-morbidities that frequently occur in adults at-risk of T2D (e.g. hypertension). The major challenge of implementing PA interventions in the management of T2D in primary care is the need to identify who provides the intervention and how the program is implemented. Not all primary care practices have access to health educators, nurses, or dietitians, and implementing group-based interventions in primary care is challenging due to scheduling and space constraints (Dunkley et al., 2014).

Family physicians have an important role in promoting healthy lifestyle change to T2D patients but have identified this role as challenging (Matthews et al., 2014a, Wylie et al., 2002, Larme and Pugh, 1998). Family physicians can heighten awareness of healthy lifestyle choices by assessing, advising, and educating patients. Hence, encouraging T2D patients to achieve healthy goals



and reviewing resources available for patients within their communities could be practised within diabetic care management (Verwey et al., 2016, Evans, 2002). Synergistically, there is good evidence that nurses and dietitians have a role in counselling and managing patients diagnosed with T2D in PHC (Hansen and Drivsholm, 2002, Aubert et al., 1998).

An overview of large-scale studies (200 papers) by Harris et al. (2003) investigated the effectiveness of PHC providers' interventions on delivering practice-based interventions that promote sustainable PA behaviour change among patients with T2D. As well, the overview examined lifestyle modification strategies, tools, and resources that have proved effective in PHC (Harris et al., 2003). Although the review gave strong recommendations for utilization of PHC physicians in promoting a healthy lifestyle, translating this evidence to practice remains a serious gap in the literature.

A review by Matthews et al. (2014b) focused on PA intervention in adults with T2D delivered within routine diabetes care only and where PA was an essential component in the outcome measures. Of the 12 selected studies in the review, eight reported an increase in PA levels, of which only five were significant. The review reported that PA interventions for adults with T2D can be effectively translated into an everyday setting delivered by a variety of trained staff/peers, in a variety of settings. The use of external organizations, behaviour change training, and tailoring of the intervention to the target population was notable (Matthews et al., 2014b).

A 12 month RCT by (Matthews et al., 2017) explored the feasibility, implementation and effectiveness of a PA consultation service by an exercise health psychologist, guided by behaviour change strategies, and tailored to stage of change for adults with Type 1 and T2D within routine diabetes care. Participant received a face-to-face consultation for 30-minutes at the beginning of the intervention followed by a follow up and further consultations at 6 and 12 months. Results showed a significant increase in the number of participants who achieved PA recommendations and better psychological wellbeing. A significant weight reduction was reported by participants, however there was no

change observed in HbA1c levels. Strengths of this study lay in: a) delivery of the intervention by a skilled psychologist; b) one to one support (consultations); c) provision of group exercise classes; d) allowing various follow up methods and; e) integration of the intervention within routine diabetes care. However, missing data from “usual care notes” and participants’ subjective PA self-reports were considered as major limitations in the study (Matthews L, 2014, Matthews L., 2013).

Work by Verwey et al. (2016) developed a counselling protocol (self-management support program) in PHC to support chronically ill patients including T2D to achieve better PA goals. The protocol was based on a five A’s model (Assess, Advice, Agree, Assist, Arrange) (Whitlock et al., 2002, Glasgow et al., 2006), from current literature insights, preferences of users and comments from experts. The protocol has a limited number of behaviour change consultations linked with specific monitoring and feedback tools. These tools are meant to be automatically shared between the patient and the service providers via an app on patients’ smartphones. The feasibility for this PA counselling protocol combined with mobile technology is yet to be tested for its appropriateness within routine practice. Nonetheless, this intervention may be limited by attracting only technology users.

A pilot empowerment-based, theory-driven education group programme by Bastiaens et al. (2009) was evaluated in a before-after design (12-18 months) in terms of emotional distress, HbA1c, BMI and actual behaviour (n=20). The programme focused on behaviour assessment, goal-setting, and problem solving. A diabetes specialist nurse jointly with a dietitian or psychologist led five 2-hour sessions and a follow-up meeting after 3 months. BMI decreased by 0.45 kg/m<sup>2</sup> (95%CI 0.01-0.89) at 12-month and by 0.53 kg/m<sup>2</sup> (95%CI 0.02-1.04) at 18-month follow-up. HbA1c declined from 7.4% (±1.3) to 6.8% (±0.8) (p=0.040). However, changes were only partly sustained at 18-month follow-up as actual behaviour changed modestly (Bastiaens et al., 2009).

In the USA, a three arm randomized trial of an intervention to improve self-care behaviours (PA and diet) of 200 African-American women with T2D in PHC was

conducted by Keyserling et al. (2002). The three groups received interventions at the: group A): clinic and community, group B): clinic only, or group C): minimal intervention. The clinic-based intervention consisted of four monthly visits with a nutritionist who provided counselling to enhance PA and dietary intake that was tailored to baseline practices and attitudes; the community-based intervention consisted of three group sessions and 12 monthly phone calls from a peer counsellor and was designed to provide social support and reinforce behaviour change goals; and the minimal intervention consisted of educational pamphlets mailed to participants. At 12 months follow-up, the trial showed a significant increase in PA behaviour in the intervention groups A and B compared to C (Keyserling et al., 2002). The intervention was acceptable to 88% of the participant who were very satisfied with clinic-based counselling to enhance PA and 86% indicated that the peer counsellor's role in the program was important. Despite the positive outcomes of this trial, larger studies were recommended to confirm, enhance and sustain the evidence.

Another multifaceted PA regimen (consultations, computer assisted behaviour change program, and phone calls) within diabetes self-management was conducted in the USA by King et al. (2006). Similar to previous trials, PA behaviour increased significantly in the intervention group. None the less, reporting acceptability, feasibility and appropriateness of the PA intervention methods in PHC was minimal.

PA interventions for people with T2D in PHC in the Arab world is scarce. No study from any Arabic speaking country was found to meet the search criteria for this literature review. Hence, evidence for culturally congruent PA interventions for people with T2D in their routine primary care remains an area for exploration.

### **3.7 Summary**

This literature review aimed to gather evidence on the effectiveness of PA interventions within routine care of people with T2D in PHC. The search was

based on the 5 systematic phases of the BEF. The first phase focused on evidence for the association between T2D and PA. Reviews have concluded that PA can significantly improve glycaemic control and diabetes-related complications. Moderate increases in PA have been shown to reduce HbA1c, and improve insulin sensitivity, fat oxidation and lipid storage in muscle. Other positive responses from increasing PA levels include improvements in the risk of cardiovascular mortality, depression; and improved health related quality of life.

The second phase of the BEF was related to methods of measuring PA which extended from subjective measures (simple observations and self-reports (diaries, questionnaires)) to more complex objective measures (physiological markers, calorimeter, doubly labelled water and motion sensors). Motion sensors (pedometers and accelerometers), although expensive are more convenient and have therefore proved popular in many PA interventions as motivational tools.

The third phase of the BEF described barriers and facilitators to PA in adults with T2D. Reported barriers to PA were several and it varied depending on the individual characteristics, disease condition, age, gender, physical and environmental condition and socio-cultural factors (e.g. religious beliefs, views on performing PA in public places specifically in women in countries of the GCC). Other identified barriers to PA within health care systems include failure to prioritize PA within diabetes care, untrained health staff to deliver PA interventions and a lack of resources.

The fourth phase of the BEF explored PA interventions in the management of T2D. Efficacy studies of PA interventions for adults with T2D differ in their delivery methods (e.g. group vs. individual counselling), setting (e.g. clinic vs. community), and duration/frequency of contact. In general, PA methods including; PA consultation, structured PA training, and technology based interventions (web based and e-interventions) seemed to overlap across the interventions with no particular preference of one method over the others.

Findings show that interventions tailored to the individual needs have greater success than general PA interventions.

Finally, the review that looked at the fifth phase of the BEF focused on evidence for implementation of PA interventions within the routine management of adults with T2D (translational research) in PHC. Limited research has looked at incorporating PA in routine practice with no consensus on the best way to include PA in PHC for T2D. It is notable that no study from the Arab world (including the GCC countries where T2D is highly prevalent) was found to have investigated incorporating PA in primary care for people with T2D. This is a notable gap in the literature in view of the importance of considering the socio-ecological model for determinants and correlates of PA across different cultures. More PA interventional studies are required to address the cultural differences specifically in the suitable BCTs to increase levels of PA, and ways to deliver PA services in PHC including feasibility, acceptability, cost, monitoring, and follow up strategies.

### **3.8 Aims**

The aim of this thesis was to address a number of gaps identified in the literature concerning the acceptable and culturally appropriate PA methods within the routine diabetes primary care setting. To do so, baseline information was needed to understand the current PA behaviour in adults with T2D and inform a suitable PA intervention design.

Research questions addressed in formative work (Chapters 4-5):

1. What is the PA levels of adults with T2D and the sociodemographic factors, physiological factors and perceptions of PA associated with meeting the World Health Organization's recommended PA levels?.
2. What are the patient's views on the appropriate PA methods in routine diabetes care within local primary health care setting?

3. What are the barriers to performing leisure-time PA in adults with T2D in Oman?
4. What are the perceptions of Health Professionals (HPs) on PA promotion for adults with T2D within a local clinical primary care setting in Oman with respect to:
  - The perceived barriers and opportunities.
  - Who should be responsible for the delivery of PA interventions?
  - The perceived intervention components that could possibly be implemented.
  - The required resources/actions to integrate PA in diabetes care.

Based on findings from the formative work, the following research questions were addressed (Chapters 6-9):

5. What is the effectiveness of the proposed PA intervention design on PA levels and the associated anthropometric, cardiovascular, metabolic changes in inactive individuals with T2D?
6. What is the effect of the proposed PA intervention on changes in general well-being?
7. What is the effect of the proposed PA intervention PA influencers (self-efficacy and social support)?
8. Were the intervention components acceptable to the participant and health care providers?

**Table 3.6: Table of PA interventions in adults with T2D**

Studies	Design/Objectives	Participant	Intervention	Outcome measures	Findings
PA consultations (Individual /group)					
UK  (Avery et al., 2016)  (Avery et al., 2015a)  (Avery et al., 2014)	A 12 months clustered randomised controlled trial	Adults with type 2 diabetes in routine primary care	A multifaceted behavioural Intervention (Movement as Medicine) to increase physical activity of patients.	Qualitative process evaluation (content, replicability and scalability) including fidelity of the intervention .	An online accredited training programme for primary healthcare professionals was developed and incorporated in the intervention.   The multifaceted behavioural intervention (Movement as Medicine) is currently undergoing evaluation in a pilot RCT.
UK  (Matthews L, 2014, Matthews et al., 2017)	12 months RCT  To measure the effectiveness of PA consultations delivered by an exercise health psychologist in PHC	N= 51	Face-to-face consultation for 30-minute at the baseline, 6 and 12 months. Intervention delivery by a professional exercise health psychologist.	IPAQ  Hospital Anxiety and Depression Scale (HADS) and the Positive and Negative Affect Scale (PANAS)	Significant increase in the number of participants who achieved PA recommendations and better psychological wellbeing. A significant weight reduction was reported by participants, however there was no

				Patient insight	change observed in HbA1c levels.
Belgium  (De Greef et al., 2011)	RCT (Three treatment arms)  To compare effectiveness of PA consultations individual versus group consultations	N=67	Group A: received three individual PA consultations by GP. Group B: received three PA group counselling sessions by a clinical psychologist. Group C: control group, received no intervention	Number of steps per day (pedometer),  PA (IPAQ)  multiple health outcomes	At 12-week follow-up: Group B significantly increased their steps per day compared with Group A and Group C (1706 versus 837 versus 313 steps, $P<0.05$ ). Group B significantly increased their self-reported PA by 82mins per day compared with Group C who reported a decrease of 21mins per day ( $P<0.05$ ). Only Group B showed a significant improvement in health outcomes ( $P\leq 0.05$ ).
Canada  (Plotnikoff et al., 2011a, Plotnikoff et al., 2010a)The Alberta Diabetes and Physical Activity Trial (ADAPT)	RCT  To explore the effects of a standard education program compared with a supplemental PA intervention on diabetes-related health outcomes	N = 96	Control group: received 11 group sessions as part of standard care. Intervention group: received an additional 2 face-to-face sessions and 13 telephone calls of decreasing frequency over 5 months. Sessions delivered by a Diabetes Educator, Personal Trainer or at 3, 6 & 12-months Nurse.	HbA1c, PA, BMI	At 12-month follow-up, the intervention group demonstrated a significant increase in PA ( $P < 0.01$ ) and cardiorespiratory fitness ( $P < 0.05$ ) from baseline to all follow-up. Also, HbA1c levels declined from baseline to all time points in the control group.



USA  (Lawler et al., 2010)	RCT  To examine the effectiveness of telephone-delivered diet and physical activity intervention on multiple behavioural outcomes	N= 434 patients with T2D or hypertension	Participants randomized to telephone counselling or usual care for 12 months	Baseline risk behaviour	Significant reductions in multiple behaviours including physical activity, fat, vegetable, or fiber intake was reported in the intervention group.
Canada  (Plotnikoff et al., 2010b)	Longitudinal cohort case studies  To determine the feasibility and efficacy of peer-led PA telephone counselling for people with T2D	N=8	Twelve weekly telephone calls of 10-15min duration delivered by peers for 3-months, aimed at increasing both aerobic PA and resistance activity	PA (GLTQ)	At 3-month follow-up: No significant change was found for aerobic PA or resistance PA.
Belgium  (Bastiaens et al., 2009)	Longitudinal pilot  A pilot study to evaluate the feasibility, acceptability and long-term effects (12-18 months) of a self-management	N=44	Five 2-h fortnightly group sessions. Additional 3-month follow-up meeting to reinforce maintenance issues. Intervention delivered by various health professionals	IPAQ  Data collection Staff support  Patient insight	Actual PA behaviour changed modestly. BMI decreased -0.45 kg/m <sup>2</sup> at 12-month and -0.53 kg/m <sup>2</sup> at 18-month follow-up. HbA1c declined from 7.4% to 6.8% and the PA was not reported due to poor reporting. These changes

	education programme for people with type 2 diabetes at the community level in primary care				were only partly sustained at 18-month follow-up.
Italy	Multi-centre RCT	N=606	Control group: standard care of PA counselling every 3-months for 12-months. Intervention group: two 75-min structured & supervised PA sessions per week in addition to standard care	HbA1c, VO2max, CV risk profile, levels of unsupervised PA	Intervention group showed significantly greater reduction in HbA1c compared with the control group (0.42% vs 0.13%, P<0.001) at 12-month follow-up and in levels of PA, VO2max, and CV risk profile.
(Balducci et al., 2009) (Balducci et al., 2008)	To improve glycaemic control via structured PA participation				
The Italian Diabetes and Exercise Study (IDES)					
UK	RCT	N=134	Control group: standard information leaflet Investigating the 12-month changes in PA and health outcomes following a PA consultation delivered by a person or in written form in T2D at baseline & 6-months. Intervention group 1: two 30-minute face-to-face consultations at baseline & 6-months using a written PA Pack. Intervention group 2: PAC in written form was given to	PA consultations, BMI, HbA1c, multiple clinical outcomes	Neither PA consultations delivered face-to-face or in written form was better than standard care at improving PA levels or health outcomes at 6 & 12-month.  A subgroup analysis of participants with low PA (baseline pedometer steps < 5000/day) found the PAC delivered face-to-face
(Kirk et al., 2009)					
Time2Act					

			participants to work through in their own time		significantly increased PA compared with the control group who showed a significant decrease at 12-month follow-up. All groups demonstrated improvements in TC, HDL, waist circumference, SBP, & DBP. HbA1c improved over 6 months.
USA  (Dutton et al., 2008)	RCT  To examine the effects of a tailored, print-based intervention for promoting PA among patients	N= 85	Control group: received a standard PA education leaflet. Intervention group: received two individual face-to-face PAC session and four follow-up support phone calls at 1, 3, 7 & 9-months.	PA (accelerometer & PAR), SOC, ETT, various clinical outcomes	Significant differences between groups were reported at 6 and 12-month follow-up in PA, HbA1c, SBP and fibrinogen.
Italy  (Di Loreto et al., 2005)	post-hoc analysis  to assess the effect of walking on increased energy expenditure on financial outcomes	N= only 179 participants were included in the financial analysis	Control group: received PA information leaflet. Intervention group: one face-to-face PAC delivered by a dietitian, in addition to PA information leaflet	PA questionnaire	A significant between-group difference was observed for changes in PA at 6 weeks. A significant between-group difference was observed for rates of progression in PA.

Netherlands  (van Sluijs et al., 2005)	RCT  Evaluated the effectiveness of a minimal intervention PA strategy (physician-based assessment and counselling for exercise [PACE]) applied in general practice settings.	N=771	Randomization took place at the general practice level. Participants were patients aged 18-70 years of age who had been diagnosed with hypertension, hypercholesterolemia, or non-insulin-dependent diabetes and had not been regularly physically active in the past 6 months.	Questionnaire to Assess Health-enhancing  physical activity (SQUASH) questionnaire, BMI	Significant positive effects was observed on PA level (mean increase of 61.6 and 61.8 minutes in total PA and leisure time PA respectively, however, the PACE intervention was not more effective than the standard PA advice on level of regular PA, stage of change in PA, or body composition.
UK  (Kirk et al., 2004)	RCT	N=70	Participants were given standard exercise information and randomly assigned to receive physical activity counselling, based on the trans-theoretical model, combined motivational theory and cognitive behavioural strategies or not in Diabetes outpatient clinic at baseline and 6 months, with phone calls at 1 and 3 months post-consultation.	7-day recall and accelerometer), stages and processes of exercise behaviour change	Between-group differences were recorded in PA (recall and accelerometer) at 12 months ( $p < 0.01$ ). Experimental participants significantly increased total activity (median difference, 115 minutes; 95% CI=73-150 minutes). Control participants recorded no significant change (median difference, -15 minutes; 95% CI=-53-13 minutes). At 12

					months, more experimental participants compared to controls were in active stages of behaviour. Between-group differences were recorded at 12 months for the frequency of using all processes ( $p < 0.01$ ), except dramatic relief and stimulus control.
Italy  (Di Loreto et al., 2003)	RCT  To assess the effect of walking on increased energy expenditure on health outcomes	N=340 (intervention)	The intervention group received an initial 30-min PA consultation by a physician, a follow-up telephone call at 1-month, followed by seven 15-min face-to-face PA consultations every 3-months compared to the control group who only had the 30-min PA.	HbA1c, PA METS , BMI, direct and indirect medical & social costs	At 2-year follow-up: No significant change in health outcomes or financial costs in participants with $< 6.8$ METS per hour per week. However, significant improvements in health outcomes and reduced financial costs was observed with energy expenditure $> 17.1$ METs per hour per week.
USA  (Keyserling et al., 2002)	Three-armed RCT  To determine whether a culturally appropriate clinic- and community-based intervention	N=200 Females only	Group A received four individual Counselling sessions by nutritionist, two group education and multiple personal phone call consultations by the peer counsellors. Group B received four individual counselling	Caltrac accelerometer  Participants insights and ratings	Significant enhancement of PA energy expenditure ( $P = 0.014$ ). Both the clinic and community components of the intervention were acceptable and feasible to participants. Participation rates for individual

The New Leaf Intervention	for African-American women with T2D will increase moderate-intensity PA		sessions, and Group C received usual care.  Intervention delivered by peers and nutritionist		counselling and telephone follow-up were high
PA Structured PA / exercise sessions					
(Johnson et al., 2012)	Non-randomized design  To evaluate a self-management program for patients with T2D within a newly established primary care network (PCN) environment	N = 110 per group	Bi-monthly blocks to either a 6-month self-management program lead by an Exercise Specialist or to usual care.	Self-reported PA  Pedometer Step counting	Results not published
Italy  (Negri et al., 2010)	RCT  To evaluate the impact of a supervised walking programme	N=59	Control group: received standard recommendations to increase PA. Intervention group: 3 supervised 45-min	HbA1C, 6-min walk test & prescription of diabetes medication	At 4-month follow-up: Intervention group showed significant reductions in HbA1c from baseline (-0.37%,  P<0.05). No between-group difference was found.

			walking sessions per week in addition to PA consultations at baseline and 2-months		Intervention group showed significant improvement in the 6-min walk test compared with the control group ( $P<0.001$ ). Reduction or discontinuation of diabetes medication was significantly greater in the intervention group compared with control group (33% versus 5%, $P<0.05$ ).
USA	RCT	N = 60	The First Step Program (FSP) is facilitated theory-based behaviour modification program for individuals with T2D, using pedometer to serve as a stimulus for walking and an instrument for individual goal-setting, self-monitoring, and feedback.	HbA1c, PA step count	The pilot testing demonstrated an immediate and dramatic increase in walking behaviour (by approximately 3,700 steps/day or 34 minutes of walking a day).
(Tudor-Locke, 2009)	To examine the effectiveness of a theory-based pedometer intervention for adults with T2D				
(Tudor-Locke et al., 2004)					
(Tudor-Locke et al., 2001)			Control group: received no intervention. Intervention group: Four weekly group meetings for the first 4-weeks that included a group walk. Motivational postcards were mailed at 6 & 10-weeks. Delivered by PA experts and diabetes educators		At 4-month follow-up: The intervention group significantly increased their PA from baseline (~3000 steps/day, ( $P<0.01$ ), a significant improvement compared to the control group ( $P<0.0001$ ). At 6-month follow-up: PA in the intervention group remained higher but not significant
The First Step Program					

			Follow up at 4 & 6-months		than the control group (P=0.17)
UK  (De Greef et al., 2010)	RCT  To investigate the benefits of a pedometer and behavioural group intervention for promoting PA	N=41	Control group: standard care of one single group-education session. Intervention group: five 90-min group educations over 12 weeks, a booster session after 22 weeks and a pedometer delivered by health post- graduates	PA (accelerometer & pedometer), weight, HbA1c and multiple health outcomes	At 12-week follow-up: Intervention group had significantly increased their steps/day vs control group (2502 versus 324 steps; P<0.05)., and reduced their sedentary behaviour by 1- hour per day (P<0.05). There was no significant effect of total PA or health outcomes. At 12-month follow-up: Intervention group maintained a significant trend for greater steps per day than the control group (924 versus -864 steps, P=0.1), however, sedentary activity returned to baseline levels.
Australia  (Furber et al., 2008)	RCT  To evaluate the effectiveness of a brief intervention using a pedometer and step-diary	N=226	Control group: received general advice to increase PA. Intervention group: additional provision of a pedometer and step diary to record daily steps for 2-week duration. Follow-up was at 2 & 20-weeks	PA (Active Australia survey)	The intervention vs control group reported significantly higher self-reported minutes of walking (P=0.01) at 2- week follow-up and achieving recommended levels of MPA (63.5% versus 41.8%, P=0.02).



Canada  (Johnson et al., 2006)	Pre & post design  To explore the effect of increased walking intensity on adults with T2D who were already achieving >10,000 steps per day	N=11	Follow-up: 1, 4 & 12-weeks Participants undertook 34 supervised walking sessions over 12-weeks where they walked at a cadence 10% faster than baseline. Participants were also encouraged to undertake supervised walking sessions at the faster cadence.	PA (accelerometer), CV fitness (Bruce-graded treadmill protocol)	At 12-week follow-up: Increased walking cadence resulted in significant improvements in cardiovascular fitness ( $P<0.05$ ). PA data not reported
USA  (Araiza et al., 2006)	RCT  To determine whether a recommendation to walk 10000 steps per day would result in significant improvements in glycaemic control, insulin sensitivity, and cardiovascular risk in patients with T2D	6-week randomized controlled trial that included 30 patients with T2D	After 10 days of baseline activity, patients were randomized into 2 groups: control and active. The control group ( $n = 15$ ) was instructed to continue with their baseline activity for 6 weeks. The active group ( $n = 15$ ) was instructed to walk at least 10000 steps per day 5 or more days per week, for 6 weeks. Data relevant to glycemic control and other parameters of health were collected at study weeks 0 and 6.	Body mass index, percentage of body fat, blood pressure, waist circumference, and resting energy expenditure (REE)	Subjects in the active group significantly increased PA by 69% during the intervention phase of the study ( $P = .002$ ) vs no change in the PA of the control group. High-density lipoprotein cholesterol and resting energy expenditure significantly increased in the active group ( $P < .05$ ). Plasminogen activator inhibitor 1 (PAI-1) activity was reduced by exercise relative to the control group ( $P = .03$ ). There were no differences in any other study parameters during the 6-week study.

Costa Rica  (Goldhaber-Fiebert et al., 2003)	Controlled clinical study  To determine whether a community-based, group-centred public health intervention addressing nutrition and exercise can ameliorate glycaemic control and associated cardiovascular risk factors in type 2 diabetic patients	N=75	Participants were randomly assigned to the intervention group or the control group. All participants received basic diabetes education. The subjects in the intervention group participated in 11 weekly nutrition classes (90 min each session). Subjects for whom exercise was deemed safe also participated in triweekly walking groups (60 min each session)	HbA1c, fasting plasma glucose, total cholesterol, triglycerides, HDL and LDL cholesterol, height, weight, BMI, and blood pressure at baseline and the end of the study (after 12 weeks)	The intervention group lost 1.0 +/- 2.2 kg compared with a weight gain in the control group of 0.4 +/- 2.3 kg (P = 0.028). Fasting plasma glucose decreased 19 +/- 55 mg/dl in the intervention group and increased 16 +/- 78 mg/dl in the control group (P = 0.048). HbA1c decreased 1.8 ± 2.3% in the intervention group and 0.4 ± 2.3% in the control group (P = 0.028).
Technology-based PA interventions (e-interventions and use of telephones)					
Australia  (Goode et al., 2011)	Clustered RCT  To examine associations of intervention dose with behaviour change outcomes in a telephone counselling intervention for	N= 228	The initiation phase (1-4 months) consisted of up to 10 weekly or fortnightly calls; the maintenance-enhancement phase (5-12 months) consisted of up to eight monthly calls.	Number of calls completed in total and during each phase.  Diet and PA were measured using validated self-report instruments.	Those completing a high number of calls were more likely to be female, white, and older than 60 years, retired, and earning less than an average weekly Australian wage. Maintenance-enhancement phase was associated with significantly greater behavioural improvement for

	physical activity and dietary change.				the following: total fat intake as percentage of calories (-3.58% [.74%]), saturated fat intake (-2.51% [.51%]), fibre intake (4.23 [1.20] g), and moderate-to-vigorous PA (187.82 [44.78] minutes).
Dutch government  (Linmans et al., 2011)	retrospective comparative medical records analysis  Evaluated a lifestyle programme, commissioned by the Dutch government, for patients with prediabetes or T2D in PHC	Intervention (n = 186)  Control (n = 2632). selected from ten primary healthcare centres	Propensity score matching on the medical records of patients who received lifestyle intervention were compared with a matched group of patients who received usual care	Exercise level, BMI, HbA1c, fasting glucose, systolic and diastolic blood pressure, total cholesterol, HDL , LDL cholesterol and triglycerides	No significant difference at follow-up in any outcome measure between either groups.
Australia  (Eakin et al., 2010)	RCT  To study the long-term effectiveness of telephone based PA interventions	N= 300	18-month, telephone-delivered, behavioural weight loss intervention focussing on physical activity, diet and behavioural therapy, versus usual care, with follow-up at 24 months	Accelerometers, HbA1c and cost analysis	Not reported

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Canada	3-armed RCT	N= 287	Group 1 received a standard information leaflet. Group 2 also received the usual care leaflet, in addition to a pedometer and print-based materials, delivered by post every 3 months for 12 months). Group 3 received the same intervention as Group 2, with the addition of tailored telephone counselling, including 15-minute	PA (pedometer), HbA1c, psychological wellbeing and the Godin Leisure-Time Exercise (GLTQ)	At 12-month follow-up:
(Plotnikoff et al., 2010a)	To explore the effectiveness of two strategies to increase PA and reduce HbA1c		Telephone consultations by trained staff, delivered with decreasing frequency over 12-months		no significant between-group change was found for any outcome. Following analysis for gender, a significant increase in step counts was observed in women between the control group and Group 3 (5964 steps, -1540 to 10338, P=0.008).
The ADAPT study					
Australia	RCT to examine the maintenance of behavioural changes 6 months following a telephone delivered PA & diet intervention	N= 434	Ten practices were randomly assigned to the telephone intervention or to usual care, Patients in intervention practices received a workbook and 18 calls over 12 months. Assessment at baseline, 4, 12 and 18 months allowed for assessment of initial and maintenance change.	PA and dietary behaviour change, quality of life, and cost-effectiveness.  PA (Active Australia survey), diet (FFQ)	Significant improvements were reported at 18-month follow-up in PA (in the intervention group $62.2 \pm 14.2$ vs comparison group $74.7 \pm 14.9$ minutes/week, $P<0.001$ ) and in dietary outcomes (greater in the intervention group, $P<0.05$ ).

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USA	RCT	N= 335	Intervention randomized to either a computer-assisted, tailored self-management intervention (N = 174) or health risk appraisal with feedback control (N = 161)	Community Healthy Activities Model Program for Seniors Questionnaire  Diet, and psychosocial assessments at baseline and 2 months	A computer-assisted, multifaceted approach that allows individuals to adjust their activity patterns showed significant improvements in PA ( $p < .01$ )
(King et al., 2006)	To evaluate the effectiveness of a multifaceted PA intervention for people with T2D that emphasized participant choice in activity selection and adjustment				
USA	RCT	N=400	Two tailored 3-h individual consultations with educator; using computer-assisted behaviour change programme. This group also received tailored phone calls in between the two visits. Control group received usual care. Intervention delivered by various health professionals		The intervention group significantly improved all PA ( $p < .01$ ) and moderate PA (metabolic equivalents $> 3.0$ , $p < .01$ ) compared to controls The results suggest that individuals are capable of to maximize their PA
(King et al., 2006)	To evaluate the effectiveness of a multifaceted PA intervention for people with T2D that emphasized participant choice in activity selection				

## **Chapter 4 : Formative work (Quantitative sub-studies): Correlates to meeting physical activity recommendations and barriers to performing physical activity**

### **4.1 Introduction**

Responding to the modest evidence on prevalence, correlates and barriers to performing PA in adults with T2D in the Arab countries namely Oman, two questionnaire based studies were undertaken to inform the PA intervention design for use in diabetes primary care in Oman.

### **4.2 Objectives**

- To describe the PA patterns of adults with T2D and examine the sociodemographic factors, physiological factors and perceptions of PA associated with meeting the World Health Organization's recommended levels of  $\geq 600$  MET-min/week.
- To identify views for integrating PA in routine diabetes care within local primary health care setting.
- To identify barriers to performing leisure-time PA in adults with T2D in Oman, and the distribution of barrier scores across different socio-demographic characteristics and perceived stages of change in PA.

The results from this chapter has been published in the the journal of the BMC Public Health (Alghafri et al., 2017c) and BMJ Open (Alghafri et al., 2017a) (see Appendix 4.1 & 4.2).

### 4.3 Methods and materials

#### 4.3.1 Study design and population characteristics

A cross-sectional interview based survey was carried out between 15th April and 6th May 2015 in Muscat, Oman. Patients with T2D attending their routine diabetes clinics, were recruited from 17 randomly selected centres of primary health care from across Oman. Inclusion criteria were age >18 years, and attending diabetes clinic for more than 2 years. Participants with type 1 diabetes, newly diagnosed patients or those who had difficulty in performing physical activity were excluded.

#### 4.3.2 Ethical considerations

Written informed consent was obtained from all participants who agreed to participate in the questionnaire. For illiterate participants, informed consent was taken from their spouse, son, daughter or other close family member (see Appendix 4.3).

#### 4.3.3 Sampling

The sample size was calculated using an estimated 15% prevalence of meeting the PA recommendations in patients with diabetes as reported previously in the 2008 Oman World Health Survey (Ministry of Health Oman, 2008). For 95% confidence limits, a response rate of 80%, and a precision of 20%, the calculated sample size was 305 participants over a total of six willayats (areas) in Muscat region (Seeb, Bausher, Amirat, Qryat, Muttrah and Muscat).

#### 4.3.4 Data collection tools and measurements

A multi-section questionnaire was designed, developed by the author and then reviewed, pilot tested for ease of administration (with 20 volunteers) and approved by the project supervisors (see Appendix 4.4):

The following data was collected:

*Socio-demographic data:* Gender, willayat, age, marital status, education, income, and work status.

*Physiological data (health status and anthropometric measures):* Collected within the last 6 months: BMI, medication, blood pressure, lipid profile, and presence of any comorbidities defined as cardiovascular, hyperlipidemia, thyroid abnormalities, renal, eye, musculoskeletal, or any other recorded condition. This information was taken directly off the electronic health information system within the routine diabetes primary care.

*Perceptions on stages of change for PA:* due to its practicality and common use in the literature, a scale made by Martin et al. (2000) was used to self-report levels of PA. Subjects who were participating in moderate physical exercise > five times per week or in vigorous exercise 3 to 5 times per week or a combination of the two for longer than six consecutive months were categorized as in 'Maintenance stage' or if < 6 months as in 'Action stage'. 'Preparation stage' was for subjects who were thinking about starting exercise or walking in the near future, or who were doing vigorous exercise < 3 times per week, or moderate physical exercise < 5 times per week. 'Contemplation stage' "getting ready" was for subjects who were thinking about starting exercise including increasing their daily walking activities in the next six months. Subjects who were not thinking about starting any physical activity in the near future were categorized as Pre-contemplation stage "not ready". Further, subjects in Preparation, Action and maintenance stages were grouped as physically active subjects, subjects in Contemplation and Pre-contemplation stages were grouped as low physically active. Additional questions were added to ascertain



whether subjects were: receiving any PA advice, felt that they undertook sufficient PA/ week, wanted to increase PA, and/or had a willingness to participate in PA interventions if these were available in their respected diabetes clinic. Two further questions asked about each participants' preferences for type of PA and suggestions how to integrate PA in the routine care diabetes in PHC.

*Levels of physical activity and sitting time:* To assess PA and sitting time GPAQ was used. This is a 16 item questionnaire developed by WHO for PA surveillance and widely used internationally (World Health Organization, 2014b). It estimates PA (intensity, duration, and frequency) performed in three domains - work (paid and unpaid including housework), travel (walking and cycling) and leisure, which includes total sitting time. PA was estimated by calculating energy expenditure using the Metabolic Equivalent (MET), the ratio of specific PA metabolic rates compared with the resting metabolic rate (one MET is equivalent to the energy cost of sitting quietly, kcal/kg/hour) (see Section 1.3.1). Total MET.min/d was calculated for each domain by first multiplying MET values by reported minutes (moderate-intensity and transport activity assigned 4MET values and vigorous-intensity activities assigned 8MET values), then adding the total MET-min of vigorous and moderate intensity activities performed (World Health Organization, 2014b). Estimated weekly PA levels were compared against WHO PA recommendations of 150 minutes of moderate-intensity PA or 75 minutes of vigorous-intensity PA per week which equates to an equivalent PA achieving at least 600 MET-minutes/week (Bull et al., 2009).

A single open-ended question regarding total sitting time is included in GPAQ as "Over the past seven days, how much time did you spend sitting or reclining on a typical day?". Participant were requested to estimate their sitting time in minutes per day. Additionally, participants were asked to report if they had ever received PA advice, to select their preferred PA, and suggest PA intervention components to be integrated within routine diabetes clinics in PHC.

*The CDC questionnaire on barriers to PA:* An English to Arabic translated CDC questionnaire "Barriers to Being Active" was used in a study in Saudi Arabia

(AlQuaiz et al., 2009) with 21 questions on seven barriers (lack of time, lack of social support, lack of energy, lack of willpower, fear of injury, lack of skill and lack of resources). Permission to use the questionnaire was obtained on November 24, 2014 (CDC USA, 2011). However, in that tool no statements on religion or environment as possible barriers to PA were included. To address this gap we undertook several procedures.

A literature search was conducted to identify possible content for the new items from studies in neighbouring countries with similar socio-economic characteristics (Serour et al., 2007, Al-Kaabi et al., 2009). Potential barriers considered questions on religious beliefs restricting PA, accepted clothing for PA and religious perceptions on PA (Ali et al., 2010, AlQuaiz et al., 2009, Amin et al., 2011). Potential environmental barriers included questions on extreme weather conditions, physical activity in summer time and availability of an appropriate environment for PA (Amin et al., 2011, Korkiakangas et al., 2011).

Each barrier category was represented by a set of three related questions (total of 27 questions) presented in random order within the questionnaire. A scoring system (CDC USA, 2011) was used to indicate how likely each statement/item was considered to be a barrier (very likely=3, somewhat likely=2, somewhat unlikely=1, very unlikely=0). Scores of the three theme-related questions were added up to provide a total score for each category of barriers. Possible scores for each barrier category ranged from 0-9. A score of  $\geq 5$  was considered as an important barrier to overcome (CDC USA, 2011).

#### 4.3.5 Validity (or accuracy) of the questionnaires

##### *Content validity*

The investigatory team of this study reviewed all versions of the questionnaires and a panel of experts in PA and diabetes care were approached to review the content of the questionnaires and suggest amendments when appropriate. Prior to field testing, the PI discussed them with a sample of 20 patients with T2D.

Adjustments were then made to ease comprehension and ensure translation to Arabic was appropriate.

#### *Face validity*

The questionnaire appeared to be an appropriate and a good measure to meet the objectives of this study through providing data on PA and sitting time and exploring barriers to PA (Bull et al., 2009).

#### *Construct validity and reliability of the CDC scale*

Based on the data from the current study, the scale quality (27 item study questionnaire) including internal consistency reliability measures were investigated through the use of factor analysis using SPSS v22 and supported by McDonald's coefficient omega using the free and open source R. (Rik Crutzen & Gjalt-Jorn Ygram Peters, 2015, R Development Core Team, 2014).

#### 4.3.6 Training

A multidisciplinary team of two nurses, one senior dietitian, one medical orderly and two doctors were recruited for data collection. They were all staff working in the Directorate General of Health Services in Muscat region who were approached for facilitating the conduct of research within the region. They were approached by the PI, informed about the study and asked if they were interested to participate in data collection at an honorary rate of 10 Omani rials per questionnaire.

A one day training on administration of the questionnaire was delivered by the national focal point on PA in Oman Ministry of Health. The training took place in 9 April 2015 in the Directorate General of Health Services DGHS, Muscat (see Appendix 4.5).

#### 4.3.7 Pilot study

Before full-scale sampling began, a small pre-test with n =25 participants from a population outside the sampled PHC was undertaken to evaluate any strengths or weaknesses of the questionnaire. All potential practical scientific issues as well as logistic constraints were evaluated and resolved before the full scale sampling. Data collection continued throughout the working hours of the diabetes clinic in the selected health centres. A list of patients attending the diabetes clinic was printed on daily basis and all booked patients were invited to participate in the study prior or after their diabetes consultations. All participants in the pilot stage were willing to participate in future interventions.

#### 4.3.8 Questionnaire administration

The questionnaire was administered during a face to face interview by the recruited research staff. The process lasted between 15 to 20 minutes. Participants were interviewed in their primary health care centres.

#### 4.3.9 Data quality / Management

Data was entered and cross-checked for quality by a nurse trained in quality assurance using check lists specific to the study (see Appendix 4.6) in a sample of 10% of questionnaires selected at random. Data entry, cross-checking and cleaning was done through Epi Info™ 7. Entered data was transferred to SPSS v22 for analysis according to GPAQ procedures (World Health Organization, 2014b).

#### 4.3.10 Statistical analyses

Descriptive statistics were expressed as mean (SD), median (IQR) or percentages and number of active cases for the total study population as appropriate. Bivariate relationships between the dependent variable of meeting WHO PA recommendations and the independent variables, namely socio-

demographic (gender, region, age, marital status, education, income, and work status), physiological (BMI, medication, duration of diabetes, blood pressure, lipid profile, and reporting comorbidities), and self-reported perceptions of PA (self-reported levels of PA, receiving PA advice, self-perceptions performing sufficient PA/week, reporting barriers to leisure PA), were tested by chi-square analyses. Potentially significant associations were further analyzed using binary logistic regression. The categories of several variables were collapsed to ensure sufficient power for the regression models and adequate numbers in all categories. For example, age was dichotomised using mean value (in years) of  $\leq 57$  vs  $> 57$ , married vs unmarried, educated vs uneducated, income  $< 500$  or  $\geq 500$ , and active vs inactive self-reported stages of PA. Backward stepwise elimination was utilised to determine statistically significant factors associated with meeting PA recommendations. The odds ratios were calculated for socio-demographic variables (against the reference categories of female, subjects aged  $> 57$  years, currently married, educated, with income of  $\geq 500$  Omani rials, and employed), physiological variables (against the reference categories of reporting existing co-morbidities), and self-reported perceptions of PA (against the reference categories of reported inactive stages of PA (“not ready” and “getting ready”) and reporting performing sufficient PA/week and reporting barriers to leisure PA). Sitting time was dichotomised around the reported data using the median value ( $\leq 705$  min/d and  $> 705$  min/d).

Preferences for PA, and the PA delivery components of interest to participants with T2D in health centres are reported as proportions of the population.

For the scale used to identify barriers to leisure PA, sum of scores from the three related questions per category (range from 0-9) were expressed as median (LQ, UQ). Correlations between the sum of scores of the nine barrier categories were tested. Chi-square analysis was carried out to identify the distribution of the high barrier scores ( $\geq 5$ ) across the studied independent sociodemographic factors. Corrected P-values (Yate’s continuity) were reported for high barrier scores against the studied independent variables.

The scale quality (27 item study questionnaire on barriers to PA) including internal consistency reliability measures were investigated through the use of factor analysis including Principal Components Analysis (PCA) using SPSS v22 (Dunn et al., 2014) and supported by McDonald's coefficient omega using the free and open source R (R Development Core Team, 2014).

## 4.4 Results

### 4.4.1 Socio-demographic

Three hundred and twelve patients were invited to participate in the study and 305 completed the questionnaire (98%), with slightly greater proportion of females than males (57.4% vs 42.6%). The majority of the sample was from Seeb willayat (41.7%), a densely populated region in Muscat. Mean (SD) age was 57 (10.8) years, more than two-thirds were married (78.8%) and almost half indicated they 'don't read or write' (48.9%). Thirty nine percent of subjects reported a household income of <500 Omani rials (Ministry of National Economy Oman, 2016) which is considered low income. Most females were housewives (77.0%). It was noted that more males than females were government employees (14.6% and 2.9% respectively) (**Error! Reference source not found.**). Meeting the PA recommendations was more common in males  $P<0.001$ , unmarried individuals  $P=0.004$ , those who completed higher education  $P=0.030$ , and those who had an income of 500-<1000 Omani rials  $P=0.008$ , and also government employees  $P<0.001$ .

### 4.4.2 Physiological

Duration of diabetes extended from two to 25 years [mean (SD) 7.59 (4.7) years, and median (range) 6 (2-25) years]. Eighty-nine percent of the sample were overweight or obese, with half classed as obese (50.2%) [mean (SD) BMI 30.96 (6.01)  $\text{kg/m}^2$ ]. More females were classed as obese compared to males

(59.4% vs 37.7%), however, a greater proportion of males were overweight compared to females (44.6% vs 34.3%). The majority of subjects were on oral hypoglycaemic drugs compared to diet only (85.2% vs 14.8%) with a quarter using insulin in addition to the oral drugs (24.6%).

Hypertension and dyslipidaemia were the most common comorbidities (71.1% and 62.0%, respectively) (**Error! Reference source not found.**). Over two-thirds of participants (71.0%) were using anti-hypertensive agents, of which most had normal BP readings (77.9%). Sixty-two percent were on statins of which the majority had fasting cholesterol (66.0%), HDL (83.0%), LDL (62.0%) and TG (67.0%) within recommended levels (as per the Oman diabetes management guidelines) (Ministry of Health Oman, 2015). Just over half the sample (58.4%) were found to have poorly controlled diabetes with HbA1c >7%. Compared to males, there were significantly more females with uncontrolled diabetes (55.0% vs 61.0%). Only 9.2% of the total sample were registered with no comorbidities in the clinical notes. There was no significant difference in meeting PA recommendations across the physiological variables except for individuals reporting no-comorbidities ( $P=0.03$ ) where meeting the recommendations was more frequent in the absence of comorbidities.

#### 4.4.3 *Perceptions on stages and status of physical activity*

Eighty-nine percent of the sample reported that PA is important in diabetes management, however the majority (83.0%) reported pre-action stages of PA; the highest proportion considering themselves “not ready” (36.7%). More males than females reported being at an “action” or “maintenance” stage of PA (7.8% vs 2.3%, and 14.0% vs 11.0%, respectively). However, the association of gender with self-reported stages of PA was not statistically significant. Despite 80.0% of the sample reporting that they received PA advice in their respective diabetes clinics, only half of them perceived that they performed sufficient PA/wk (49.0%) (see Table 4.3). Meeting PA recommendations was higher in individuals reporting being at “Action” stage of PA  $P<0.001$ , and/or reporting no barriers to PA.

**Table 4.1: Sample characteristics (socio-demographic variables) and prevalence of meeting physical activity recommendations**

Sample characteristics	Total sample n =305(%)	Meeting physical activity recommendations  n=66(21.6%)	Not Meeting physical activity recommendations  n=239(78.4)	P-value
Gender				<0.001*
Male	130(43)	45(35)	85(65)	
Female	175(57)	21(12)	154(88)	
Willayat				0.060
Alamirat	42(14)	4(10)	38(90)	
Bousher	37 (12)	3(8)	34(92)	
Muscat	22(7)	3(14)	19(86)	
Muttrah	63(21)	23(37)	40(63)	
Quryat	14(4)	2(14)	12(86)	



Aseeb	127(42)	31(24)	96(76)	
Age categories (years)				0.050
<40	21 (7)	10(48)	11(52)	
40-49	54 (18)	14(26)	40(74)	
50-59	98 (32)	24(24)	74(76)	
60-69	92 (30)	15(16)	77(84)	
≥70	40 (13)	3(8)	37(93)	
Marital status				0.004*
Unmarried	8(3)	3(38)	5(63)	
Currently married	240(79)	57(24)	183(76)	
Separated/divorced	20(6)	5(25)	15(75)	
Widowed	37(12)	1(3)	35(97)	

Education				0.030*
Don't read or write	149(49)	18(12)	131(88)	
Less than primary	49(16)	8(16)	41(84)	
Primary completed	28(9)	8(29)	20(71)	
Preparatory completed	27(9)	13(48)	14(52)	
Secondary completed	30(10)	11(37)	19(63)	
College completed	10(3)	4(40)	6(60)	
Higher education completed	11(4)	5(45)	6(55)	
Income (Omani Rials)				0.008*
<500	120(39)	22(18)	98(82)	
500-<1000	100(33)	35(35)	65(65)	
1000-<1500	17(6)	4(24)	13(76)	
≥1500	14(5)	3(21)	11(79)	

No answer	54(17)	2(4)	52(96)	
Employment		0.02		<0.001*
Government employee	24(8)	12(50)	12(50)	
Non-government employee	35(11)	13(37)	22(63)	
Self-employed	12(4)	4(33)	8(67)	
Retired	77(25)	19(25)	58(75)	
Unemployed	157(52)	16(10)	141(90)	

\*significant  $p < 0.05$  based on chi-square analysis

**Table 4.2: Sample characteristics (physiological variables) and prevalence of meeting physical activity recommendations**

Sample characteristics	Total sample n =305(%)	Meeting physical activity recommendations  n=66(21.6%)	Not Meeting physical activity recommendations  n=239(78.4)	P-value
BMI (kg/m2)				0.6
Normal	34(11)	7(21)	27(79)	
18.5-24.99				
Overweight	118(39)	29(25)	89(75)	
>25-29.99				
Obese	153(50)	30(20)	123(80)	
>30				
Current medication				
Blood pressure lowering	217(71)	45(21)	172(79)	0.5
Lipid lowering	189(62)	40(21)	149(79)	0.8
Oral-hypoglycaemic drugs	260(85)	53(20)	207(80)	0.2
Insulin	75(25)	12(16)	63(84)	0.2
Diet control	45(15)	32(71)	13(29)	0.2
Duration of diabetes (years)				0.5
<5	140 (46)	37(26)	103(74)	
6 to 11	117(38)	18(15)	99(85)	
12 to 18	33 (11)	6(18)	27(82)	
>18	15 (5)	5(33)	10(67)	

Blood pressure (systolic/diastolic) mmHg**				0.5
Within target (<140/<80)	237(78)	49(21)	188(79)	
High (≥140/≥80)	68 (22)	17(25)	51(75)	
HbA1c (%)**				0.3
Normal ≤7%	127 (42)	31(24)	96(76)	
High >7%	178 (58)	35(20)	143(80)	
Fasting lipid profile (mmol/L)**				
Cholesterol	201(66)	44(22)	157(78)	0.9
Within target (< 5.0)				
Cholesterol	104(34)	22(21)	82(79)	
High (≥5.0)				
HDL	254(83)	58(23)	196(77)	0.3
Within target (>1.0)				
HDL	51(17)	8(16)	43(84)	
Less protective (≤1.0)				
LDL	188(62)	40(21)	148(79)	0.8
Within target(<2.6)				
LDL	117(38)	26(22)	91(78)	
High (≥2.6)				
TG	205(67)	42(20)	163(80)	0.5
Within target(<1.7)				
TG	100(33)	24(24)	76(76)	

High( $\geq 1.7$ )			
Comorbidities			0.03*
Yes	277(91)	55(20)	222(80)
No	28 (9)	11(39)	17(61)

\*significant  $p < 0.05$  based on chi-square analysis

\*\* Oman diabetes mellitus management guidelines (2015)

Body mass index (BMI), Glycated haemoglobin (HbA1c), High-density lipoprotein (HDL), Low-density lipoprotein (LDL), Triglycerides (TG)

**Table 4.3: Sample characteristics (perceptions of stages and status of PA) and prevalence of meeting physical activity recommendations**

Sample characteristics	Total sample n =305(%)	Meeting physical activity recommendations  n=66(21.6%)	Not Meeting physical activity recommendations  n=239(76.4%)	P-value
Self-reported stages of change in physical activity				<0.001*
Not ready (Pre-contemplation)	112(37)	8(7)	104(93)	
Getting ready(contemplation)	95(31)	24(25)	71(75)	
Preparation	46(15)	14(30)	32(70)	
Action	14(5)	7(50)	7(50)	
Maintenance	38(12)	13(34)	25(66)	
PA advice				0.2
Yes	245(80)	49(20)	196(80)	
No	60(20)	17(28)	43(72)	

Reporting performing sufficient PA/wk				0.05
Yes	150 (49)	39(26)	111(74)	
No	155(51)	27(17)	128(83)	
Reporting barriers to performing PA				<0.001*
Yes	177(58)	24(14)	153(87)	
No	128(42)	42(33)	86(67)j	
Mean sitting time (SD) min/d	688.1(143.5)	637.4(141.2)	702.0(141.3)	<0.001***

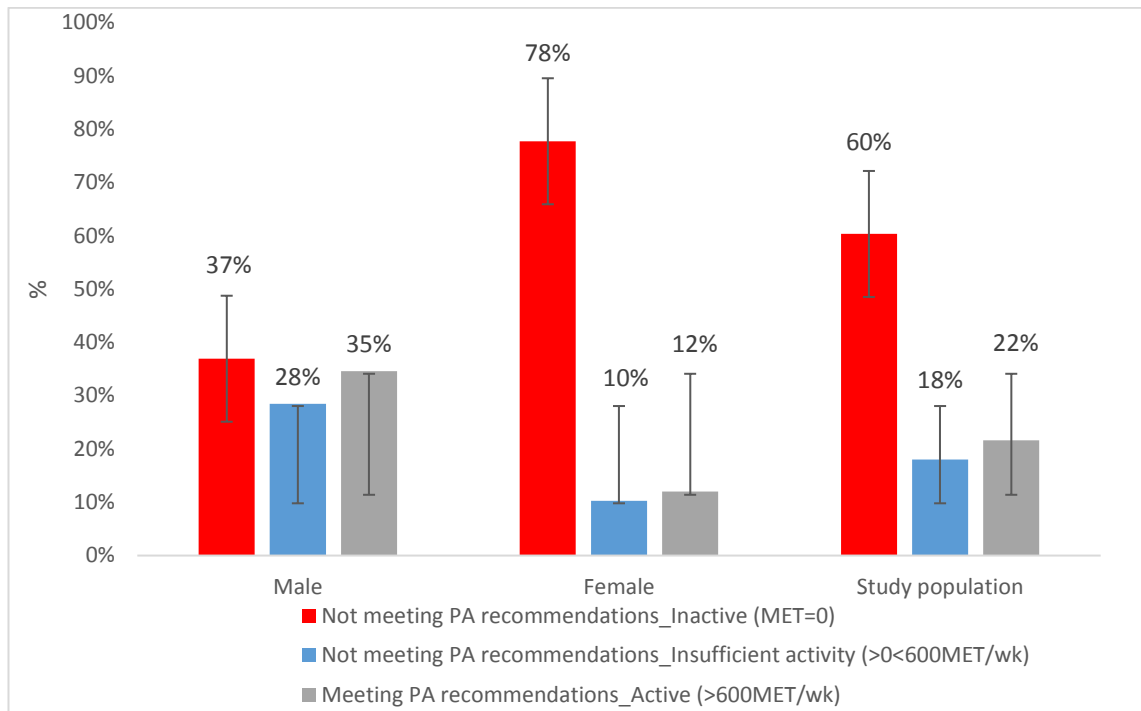
\*significant  $p < 0.05$  based on chi-square analysis

\*\* Oman diabetes mellitus management guidelines (2015)

\*\*\* Non parametric test (Mann-Whitney U test)

#### 4.4.4 Physical activity and sitting time

Overall, one fifth (21.6%,  $n=66$ ) of the study population met the recommended WHO PA levels of  $\geq 600$  MET-min/week (34.6% males vs 12.0% females). The mean (SD) and median (25th, 75th percentiles) MET.min/week count achieved was 680 (2347) and 0 (0, 420) min/wk. Mean (SD) and median (25th, 75th percentiles) MET.min/week value for individuals meeting the recommendations was 2882(4405) and 1680(960, 2790) min/wk, vs 73 (145) and 0 (0, 0) MET.min/week for individuals not meeting them. More than half of the population [60.3% ( $n= 184$ ) (36.9% males vs 77.7% females)] had PA levels= Inactive (MET =0). On the other hand, 18% of the population [( $n=55$ ) (28.5% males vs 10.3% females)] had levels of PA MET.min/week  $>0$  to  $<600$  MET.min/week classified as insufficient activity (**Error! Reference source not found.**).

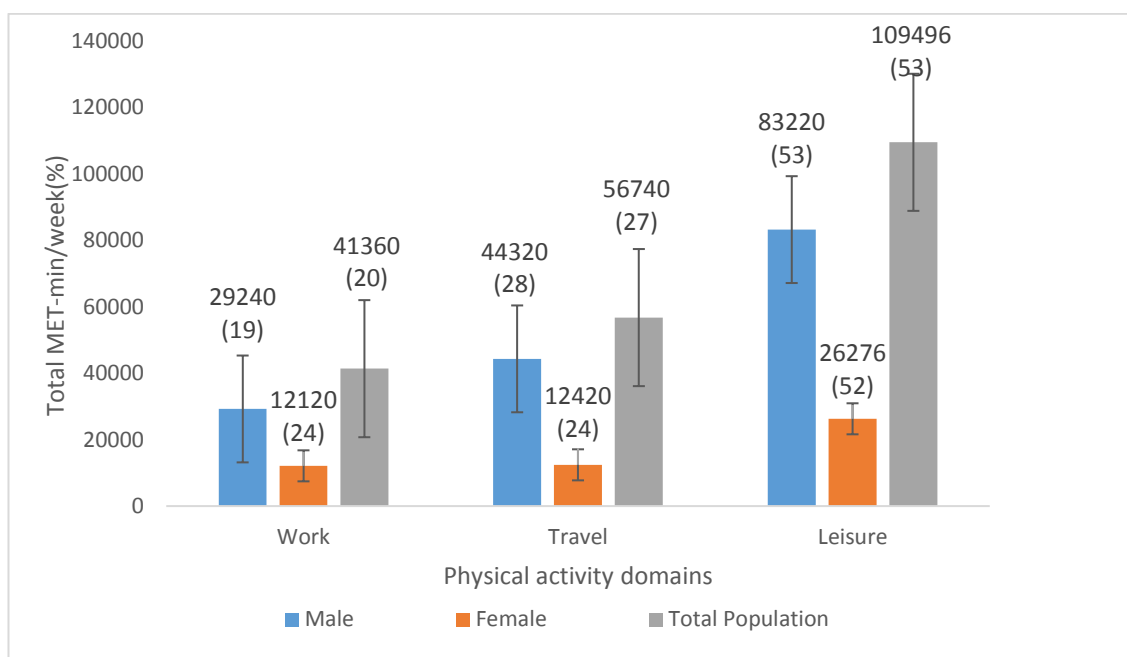


Error bars equals standard error

**Figure 4.1: Proportion of Omani adults with type 2 diabetes meeting WHO physical activity recommendations, by gender**

Just above half of the total MET.min/week from all three domains (207596 MET-min) was achieved through the 'leisure' domain (109496 MET-min). This was equally true for both males and females, as illustrated in **Error! Reference source not found.** Compared to males, females were less physically active across the three PA domains (work, travel and leisure).





**Figure 4.2: Distribution of total MET-min count (%) across the activity domains (work, Travel and work)**

#### 4.4.5 Multivariate analysis

Binary regression analysis showed that the odds of meeting PA recommendations was significantly higher in males compared to females (OR 4.8, 95%CI 2.5 to 9.1), in individuals  $\leq 57$  years old compared to individuals  $> 57$  years old (OR 3.0, 95%CI 1.6 to 5.9), in individuals reporting 'active stages' of PA compared to those 'not active' or 'getting ready' for PA (OR 2.2, 95% CI 1.2 to 4.1) and in those who reported no barriers to performing PA compared to those who reported barriers (OR 2.7, 95%CI 1.4 to 4.9) (**Error! Reference source not found.**).

Looking at domain specific correlates of meeting PA recommendations, for the work domain, meeting recommendations was more likely in those reporting they were in 'active stages' of PA (OR 4.8, 95%CI 1.4 to 15.8) and reporting no barriers to PA (OR 4.4, 95%CI 1.2 to 16.5). Males (OR 9.2, 95%CI 3.2 to 5.9), individuals  $\leq 57$  years (OR 3.1, 95%CI 1.3 to 7.6) and reporting no barriers to PA (OR 2.5, 95%CI 1.1 to 5.8) were more likely to meet PA recommendations in

travel domain. Males, individuals  $\leq 57$  years and those reporting active stages of PA were more likely to meet PA recommendation in the leisure domain (OR 3.1, 95%CI 1.4 to 6.6, OR 3.1, 95%CI 1.4 to 7.1 and OR 5.5, 95%CI 2.5 to 12.0, respectively) (explanatory table is presented in Appendix 4.7).

**Table 4.4: Correlates of meeting WHO PA recommendations in adults with type 2 diabetes**

Parameter n=305 (%)	Meeting physical activity recommendations (%)	Not meeting physical activity recommendations (%)	OR	95%CI	Sig
<b>Gender:</b>					
Males=130(42.6%)	45(35)	85(65)	4.8	2.5-9.1	<0.001
Females=175(57.4%)	21(12)	154(88)	Ref	.	.
<b>Age:</b>					
$\leq 57=155(50.8)$	45(29)	110(71)	3.0	1.6-5.9	0.001
$>57=150(49.2)$	21(14)	129(86)	Ref	.	.
<b>Self-reported stages of PA</b>					
Not/getting ready (inactive)=207(67.9)	32(15)	175(85)	0.5	0.2-0.8	0.009
Preparation/action/main tenance (active)= 98(32.1)	34(35)	64(65)	Ref	.	.
<b>Reporting barriers to performing PA</b>					
No Barriers= 128(42)	42(33)	86(67)	0.4	0.2-0.7	0.002
Reported Barriers=177(58)	24(14)	153(86)	Ref	.	.

#### 4.4.6 Correlates of sitting time

Sitting time ranged from 240 to 890 min/d (4-15 hours). Females reported longer sitting time than males. Median (25<sup>th</sup>, 75<sup>th</sup> percentiles) sitting time in females was 720 (600, 780) min/d vs 660 (600, 840) min/d in males. Gender was not significantly associated with prolonged sitting ( $P=0.4$ ). Age was the only significant correlate for longer sitting time. Older individuals ( $>57$  years) had significantly longer sitting time compared to individuals  $\leq 57$  years (OR 2.8, 95% CI 1.7 to 4.6).

Median (25<sup>th</sup>, 75<sup>th</sup> percentiles) sitting time was 705 (600, 780) min/d. Individuals meeting PA recommendation had significantly lower sitting time of 600 (540, 720) min/d than 720 (600, 840) min/d in individuals not meeting the recommendation (see Table 4.3).

#### 4.4.7 Preferences for PA and intervention delivery components

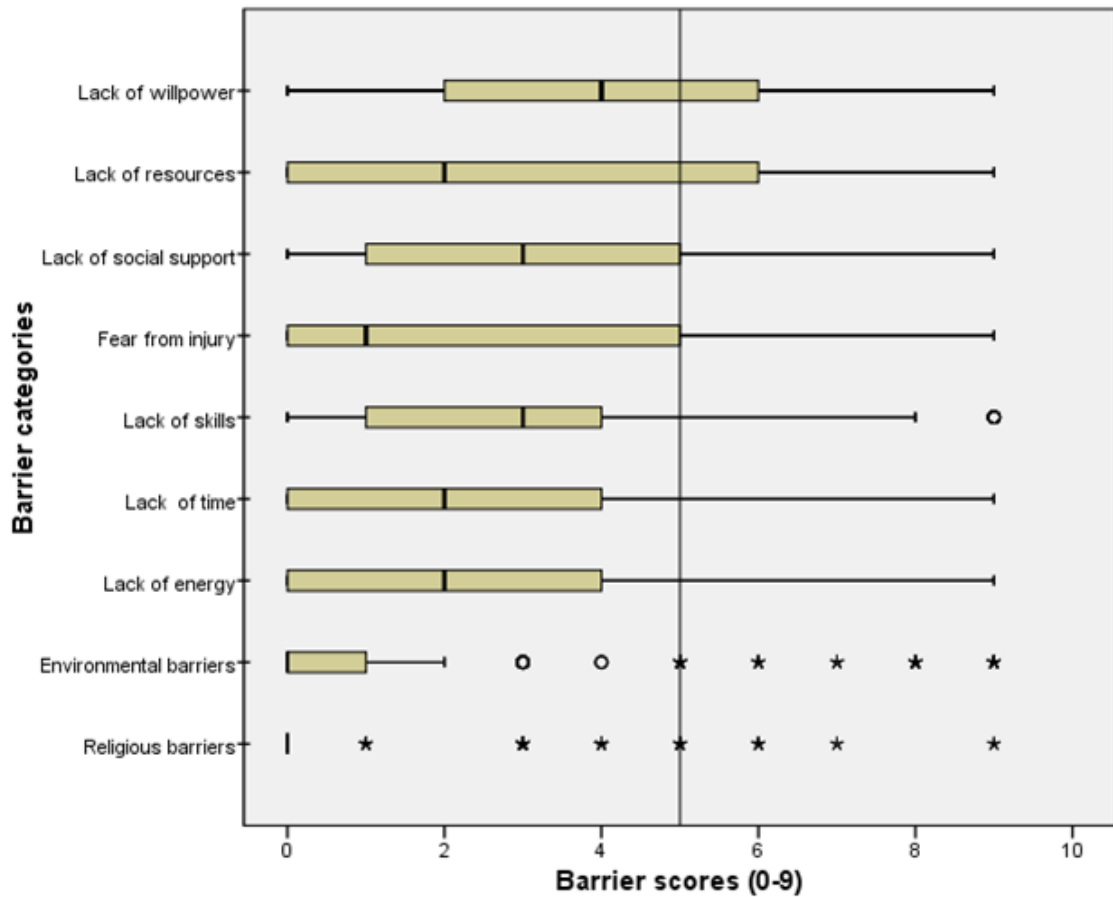
When participants were asked to select their preferred PA for which they would like to get support, walking was of interest to 97.4% of the study population. Just over a third of the sample (38.0%) were interested in PA consultations/clinics integrated in routine diabetes care in the primary care setting followed by structured PA exercises (13.0%) and PA referrals (6.0%). Whilst 27.0% suggested mixed PA components including consultations/clinics, structured exercises, and referrals to PA facilities, other participant, reported “Don’t know” and “no preferred PA component” (12.0% and 4.0% respectively).

Less than half of the sample reported they “did not know” who should be responsible for PA in diabetes care (42.0%). The diabetes doctor was selected by a fifth of the population (22.0%) followed by the dietitian (9.0%), and 27.0% reported various other healthcare professional namely physiotherapists, PA experts, diabetes nurse and health educator.

#### 4.4.8 CDC questionnaire on barriers to leisure PA

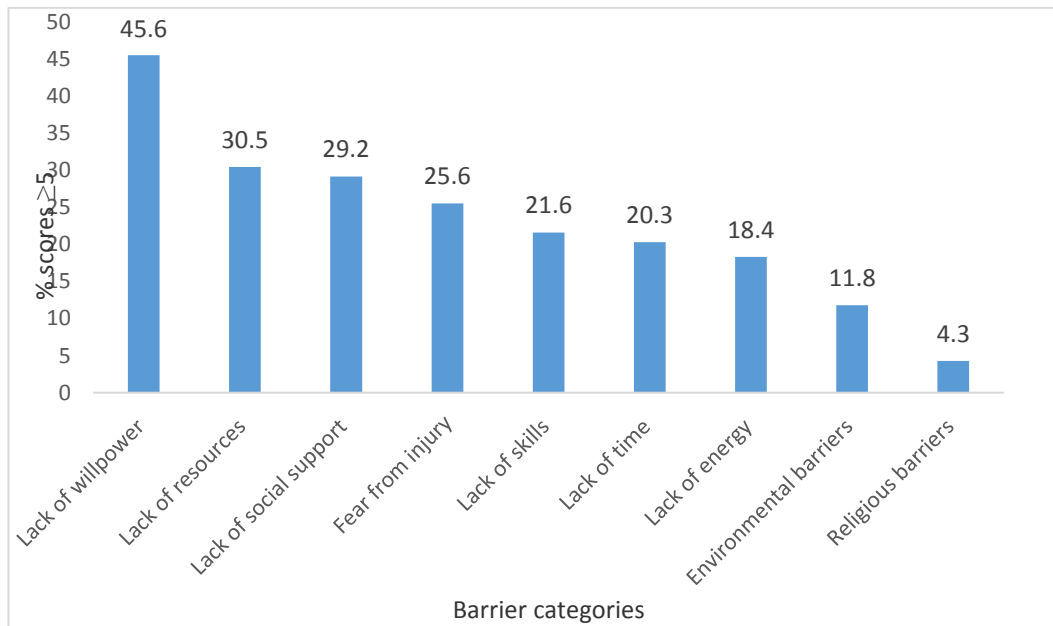
For the 27 items/questions scale, McDonald's coefficient Omega was equal to 0.750 indicating moderate reliability of the scale (Dunn et al., 2014). Further, PCA analysis with nine components solution generally supported the categorisation of the reported subscales (three questions per barrier category) in barriers to performing PA mainly component 2, 4, 5, 6, and 9 representing fear from injury, environmental barriers, religious barriers, lack of willpower, and lack of resources respectively (see Appendix 4.4). Cross contributions were evident in four out of the nine extracted components namely component 1 (lack of willpower, time, energy and skills), component 3 (lack of time and energy), component 7 (lack of social support and skills), and component 8 (lack of social support and energy) (see factor analysis in Appendix 4.8). Each of the subscales for the nine studied barriers had good reliability [McDonald's coefficient Omega was equal to 0.9]. Based on this, further results are presented using sum scores.

Most of the population, 97.7% (n=298), reported at least one barrier to performing leisure physical activity: median (25th and 75th percentiles) was 6 (4, 7). Except for reporting lack of willpower and lack of resources, population distributions were not normal across all reported barrier categories. Median sum scores were all <5 as illustrated in **Error! Reference source not found..**



**Figure 4.3: Box and Whisker plots for the reported barrier sum scores of 0-9 (high scores defined as  $\geq 5$ )**

Categorizing barrier scores to  $<5$  and  $\geq 5$  (significant barrier) highlighted that 'lack of willpower' ( $n=139$ ), 'lack of resources' ( $n=93$ ) and 'lack of social support' ( $n=89$ ) were the most frequently reported 'significant barriers' to physical activity (**Error! Reference source not found.**). Barriers found to be statistically significant in both males and females were lack of willpower (41.5% m: 48.6% f) and lack of resources (32.3% m: 29.1% f). In addition, lack of time in males (26.9%) and lack of social support in females (35.4%) were also noteworthy (**Error! Reference source not found.**).



**Figure 4.4: Percentage of reported high barrier scores ( $\geq 5$ )**

Distribution of high barrier score ( $\geq 5$ ) across sociodemographic factors and self-reported stages of change in PA differed across the nine barrier categories. “Lack of time” scored highly by males, younger adults and those who were married, employed or educated. Additionally, “Lack of social support” was scored highly by females and “Lack of energy” by employed, or educated adults. However, “Lack of willpower” scored highly by individuals with lower income, or at inactive stages of PA. Moreover, “Fear of injury” scored highly by older adults, unemployed, uneducated, or individuals reporting in-active stages of PA. Furthermore, “Lack of skills” scored highly by females, younger adults, and unemployed or uneducated. “Lack of resources” on the other hand, scored highly by married adults or with lower income. It is notable that the religious and environmental barriers had no significant different in distribution across any of the factors examined (**Error! Reference source not found.**).

**Figure 4.5: Distribution of significant high barrier score ( $\geq 5$ ) across the studied sociodemographic factors and self-reported stages of change in PA (n=305)**

(%) Scores $\geq 5$	Lack of time	Lack of social support	Lack of energy	Lack of willpower	Fear of injury	Lack of skills	Lack of resources	Religious barriers	Environmental barriers
Gender:									
Male	26.6	20.8	21.5	41.5	24.6	13.1	32.3	3.8	10.0
Female	15.4	35.4	16.0	48.6	26.3	28.0	29.1	4.6	13.1
Corrected chi-square	5.4*	7.1*	1.2	1.2	0.04*	8.9*	0.2	0.001	0.4
Age:									
$\leq 57$	27.7	26.5	21.3	45.8	18.7	16.1	33.5	4.5	12.3
$> 57$	12.7	32.0	15.3	45.3	32.7	27.3	27.3	4.0	11.3
Corrected chi-square	9.7*	0.9	1.4	0.0	7.1*	5.0*	1.1	0.00	0.0

Marital status:									
Unmarried	10.8	35.4	16.9	43.1	30.8	24.6	18.5	7.7	13.8
Married	22.9	27.5	18.8	46.3	24.2	20.8	33.8	3.3	11.3
Corrected chi-square	3.9*	1.2	0.0	0.1	0.9	0.2	4.9*	1.4	0.1
Employment:									
Un-employed	12.4	31.6	14.5	47.0	29.5	25.6	31.6	4.7	11.5
Employed	46.5	21.1	31.0	40.8	12.7	8.5	26.8	2.8	12.7
Corrected chi-square	37.0*	2.4	8.8*	0.6	7.2*	8.5*	0.4	0.1	0.0
Education:									
Un-educated	11.4	33.6	13.4	45.6	35.6	28.2	29.5	6.0	10.7
Educated	28.8	25.0	23.1	45.5	16.0	15.4	31.4	2.6	12.8
Corrected chi-square	13.2*	2.3	4.1*	0.0	14.2*	6.6*	0.1	1.5	0.1



Income:									
<500	16.7	26.7	21.7	54.2	20.8	23.3	40.0	5.8	8.3
>=500	22.7	30.8	16.2	40.0	28.6	20.5	24.3	3.2	14.1
Corrected chi-square	1.3	0.4	1.1	5.3*	1.9	0.2	7.7*	0.6	1.8
Self-reported stages of PA:									
Not active	18.4	28.5	17.9	50.7	31.9	24.2	29.5	4.3	13.5
Active	24.5	30.6	19.4	34.7	12.2	16.3	32.7	4.1	8.2
Corrected chi-square	1.2	0.1	0.	6.2*	12.5*	2.0	0.2	0.00	1.4

\* Significant at  $P < 0.0$

## 4.5 Discussion

The aim of this formative sub-study was to estimate levels of PA, sitting time and the factors associated with meeting PA recommendations and prolonged sitting time in adults with T2D in Oman. Additionally, barriers to leisure time PA were explored. The current work contributes to the limited literature on PA internationally and in particular PA patterns in patients with diabetes in the GCC. It is likely that the response rate in this study was high due to collecting data within clinical settings during their waiting time for their routine diabetes clinics.

### 4.5.1 *Prevalence and correlates of meeting WHO physical activity recommendations*

Evidence on activity levels in populations with T2D is variable across countries. However, low levels of PA in T2D populations have been reported in several studies (Heiss and Petosa, 2014) including those from Arabic speaking countries (Sibai et al., 2013, Al-Otaibi, 2013, Mabry et al., 2010a, Serour et al., 2007). Whilst the proportion of the target group achieving PA recommendations in this study is higher than national levels (15%), activity levels are much lower than those reported in populations with T2D in the UK (34%) (Thomas et al., 2004) and USA (36 to 50%) (Morrato et al., 2007a). Of greatest concern is the fact that more than half (60.3%) of this study sample, compared to 55% in similar studies, reported no activity (MET=0) (Hays and Clark, 1999), indicating highly inactive lifestyles. It is however plausible that the use of different study tools may have contributed to disparities in PA levels across studies. The inactivity levels in this study population is disappointing in view of the consistent evidence on the physiological, metabolic and haemodynamic benefits of PA in the management of T2D (American Diabetes Association, 2010).

Being male, younger (<57 years), reporting being at “active stages” of PA and reporting “no barriers” to performing PA were significantly associated with meeting PA recommendations in this study population. The global trend of male dominance in meeting the PA recommendation was prominent in both the travel and leisure domains. Higher travel activity levels in males could be due to cultural and religious factors in Arabic and Muslim countries. Congregational prayers in mosques are considered to have more social and spiritual benefit than praying by oneself. Unlike females, males walk to and from the mosques five times every day for their daily prayers (every neighbourhood has access to mosques) that are within community’s walking distances (Muhammad Al-Munajjid, 2016). This may additionally be augmented by a lack of gender specific facilities and safe places for females to perform PA activity as reported in neighbour countries namely UAE and Saudi Arabia (Ali et al., 2010, Amin et al., 2011, AlQuaiz et al., 2009). Hence gender segregated PA promotional interventions for adults with T2D should target females who are more vulnerable to inactive behaviour and uncontrolled diabetes, as indicated in this study.

The time spent in leisure activity contributed the most to the overall activity levels, (notably in men) Leisure time PA has been reported to be significantly associated with reduced mortality risks (20% to >37%) and favourable cardiovascular outcomes (Colberg et al., 2010a). No clear association (positive or inverse) was observed for work or travel PA with the overall achievement of PA recommendations or health outcome (Hallman et al., 2015). In general, individuals who had not met PA recommendations in the current study had higher blood pressure, HbA1c, lipid profile, and more comorbidities. Hence, PA promotional interventions should consider opportunities within activity domains: work, travel and most importantly leisure for sub-populations with T2D across the various cultures. Meeting PA recommendations in travel and leisure domains was also seen to be more likely in younger individuals. Younger individuals in the current study have less comorbidities and hence may experience less discomfort compared to older individuals with T2D who might fear injuries (Heiss and Petosa, 2014).

In the current study, self-reported PA stages of change namely “pre-contemplation” and “contemplation” was associated with low activity levels specifically in work and leisure domains. The fact that more than half of the study population were at in-active stages of PA raises concerns in view of the current diabetes care in Oman that specifies the provision of advice on PA (Ministry of Health Oman, 2015). This is a critical finding as the majority (80.0%) of the study population indicated that although they had received PA advice, this was not associated with being physically active or meeting PA recommendations. The current PA advice in routine diabetes care, which is a simple and general PA message (Ministry of Health Oman, 2015), could usefully incorporate behaviour change techniques to promote stage progression for individuals with T2D from pre-action to action and maintenance stages of change.

Identification of PA barriers across activity domains is an important process. Barriers identified to performing PA in the current study was associated with not meeting the PA recommendations specifically in work and travel activity domains. Hence, opportunities for culturally suitable active workplaces and transportation should be identified and considered.

#### 4.5.2 Prevalence and correlates of longer sitting time

Despite using the same measurement tool, the average sitting time in the current study population was almost six times higher (705 min/d) than what has been reported locally in the general population of 120 min/d (Mabry et al., 2013). This disparity could be attributed to different characteristics including disease condition of the current population. Similarly, the average sitting time in the current study was more than double the time spent sitting by adults with T2D in Canada of 278 min/d (Brazeau et al., 2015a), however different measurement tools were used. Given the evidence on the increased risk of cardio-vascular mortality with long sitting time on health (Bell et al., 2014a), PA interventions should emphasise shorter and interrupted sitting time especially for vulnerable sub-groups with T2D. However, further research for the

population with T2D on domain-specific (work, travel and leisure) sedentary behaviours is necessary to plan for appropriate public health interventions targeting more PA and less sedentary behaviour.

Longer sitting time in the current study was associated with older age (>57years). This finding corresponds to a study in the USA that reported increased sedentary time with age for both men and women in the general population (Healy et al., 2011a). Conversely, factors significantly associated with longer sitting time in the study in Sur were younger age, employed individuals, higher BMI (in females) and higher education (in males). However, no significant associations between longer sitting time and socio-economic or clinical variables in a T2DM population in a study in Canada was evident, the exception being for non-immigrants, and those with a university degree for whom sitting times (min/d) were found to be greater (Brazeau et al., 2015b). Variations in significant correlates across the different studies may be attributed to differences in definitions of sedentary behaviour including insufficient PA and sitting time, and differences in measurement tools (Pate et al., 2008a).

#### 4.5.3 Preferred physical activity by adults with T2D

Similar to a study in Scotland in adults with T2D (Thomas et al., 2004), the current study reported walking as the preferred activity over running, cycling, swimming and other leisure activities. Walking interventions combined with pedometers as motivational tools have been shown to improve PA behaviour in the general population and adults with T2D (Wen et al., 2014, Ogilvie et al., 2007). Hence, irrespective of culture, walking can be considered as an appropriate method of PA promotion for adults with T2D. Whilst all walking types means a reduction in sedentary time, the added value of moderate to vigorous PA should be emphasised (Di Loreto et al., 2005) (see Section 3.2.1).

#### 4.5.4 Perceptions of adults with T2D on PA intervention components for possible integration into routine primary diabetes care in Oman

In the current study population, just over a third were interested in PA consultations in routine diabetes care. In terms of who participants felt they would prefer to be responsible in delivering PA services within diabetes care, 40% selected “don’t know” a fifth (22%) preferred diabetes doctors. The fact that participants were unsure about their preferred health care provider for PA promotion provides opportunity to utilize a range of health care providers to endorse PA within diabetes care, e.g. health educators, dietitians or diabetes nurses. For example, a study in UAE showed favourable outcomes by utilizing pharmacists in PA promotional activities within PHC (Abduelkarem and Sackville, 2009) .

Furthermore, effectiveness of PA consultations linked to behaviour change techniques in increasing PA behaviour in the population with diabetes has been consistent in several reviews and randomized control trials carried out in the UK, Canada, USA and Belgium (Avery et al., 2015a, Plotnikoff et al., 2011a). This approach has yet to be investigated in the Arab world.

#### 4.5.5 Barriers to leisure time physical activity (findings from the CDC questionnaire)

In the current study, lack of willpower was frequently reported by individuals from low income households. This finding is similar to a Canadian study which reported a negative association between financial position and intention to participate in leisure-time PA in adults with T2D (Boudreau and Godin, 2009). Additionally in a study in the USA, older individuals with low income and individuals with depression, had low participation in social activities and had lower odds of engaging in PA (Plow et al., 2011). A more recent study in Finland showed that there is an association between income and PA, but the association is gender-specific (positive for women and null for men) and depends on the measurement type of PA (Kari et al., 2015). None the less,

more evidence is needed to explain how income alters the willpower or vice-versa for performing leisure PA in Arabic speaking countries, including Oman. Lack of willpower was more likely to be reported by individuals at inactive stages of physical activity (pre-contemplation or contemplation stages of physical activity) than those in active stages. Progressive stages of behavioural change according to the trans-theoretical model were direct correlates to PA in a review article by Trost et al. (2002) and direct determinants in another by Van Stralen (van Stralen et al., 2009). This finding supports the need for programs to help raise self-willpower/determination through a stepped process of behaviour change from inactive (pre-contemplation) to active stages of PA (action and maintenance) (Kirk et al., 2010). Interestingly, fear of injury was the only other reported barrier significantly different between individuals at inactive vs active stages of change in PA. This could be explained by possible physical constraints pertaining to older age (Plow et al., 2011) and existing comorbidities in the current study population triggering fear of injuries associated with PA.

Limited resources including high cost and limited facilities for PA have been reported as significant barriers to PA across different cultures (Booth et al., 2013, Mier et al., 2007). In the current study, limited resources were reported as significant by individuals who were married and those with low income. Married individuals could have more financial commitments to their families especially in the GCC countries where extended families are common (GCC statistical center, 2010). Low income was similarly reported as a barrier in a Saudi population, possibly due to the perceived high cost of utilising PA facilities (AlQuaiz et al., 2009). This may reflect a narrow view on what constitutes PA and a misconception that expensive equipment is required. Hence, irrespective of culture, interventions promoting cost neutral PA such as walking in populations would be highly desirable to overcome this barrier (Bird et al., 2013, Alghafri et al., 2017d).

Lack of social support was frequently reported by females in this study. Meeting cultural norms and social expectations related to safety, security and conservative dress mainly for females were reported as barriers to PA in South

Asian (Pakistani and Indian) British populations (Korkiakangas et al., 2009, Lawton et al., 2006) and populations in Arabic counties such as Qatar (Donnelly et al., 2012). Evaluation of interventions to provide the necessary social support and networks to PA specifically for women with T2D, particularly in the countries of the GCC are warranted. Activities including group-based activities and buddying are worth further investigation (Bastiaens et al., 2009, Matthews L., 2013, Barrera et al., 2008) although may not be feasible within a clinic setting.

Other reported barriers such as fear of injury and lack of skills varied across subgroups, in particular, older, unemployed, and uneducated individuals. Older individuals with T2D are more vulnerable to have poor vision and osteoarthritic changes that may cause fall and injuries (Alberti and Zimmet, 1998). Moreover the negative influence of pain to PA in older population with T2D was reported in western countries (Thomas et al., 2004) and hence potential barriers to individuals' participation. These results suggest that programs to promote PA should be individualized for type, frequency and intensity of PA and incorporate safety measures to prevent PA induced pain and injuries in older individuals such as safe walking areas (Borschmann et al., 2010).

Lack of time is a highly cited barrier to PA in the general population as well as populations with diabetes (Egan et al., 2013, Korkiakangas et al., 2011, Hume et al., 2010, Korkiakangas et al., 2009, Mier et al., 2007, Lawton et al., 2006, Donahue et al., 2006, Thomas et al., 2004). However, unlike the study by Alquaiz (2009), significant scores for lack of time in the current study were higher in males compared to females (AlQuaiz et al., 2009) along-with a lack of energy. This may be a reflection of the fact that more males than females were educated and employed. This perception of 'lack of time', in addition to family and social commitments may compete for their time for PA especially if individuals are younger and married. This discussion highlights the importance of changing people's perceptions of PA but also consideration of opportunities in other PA domains namely work and travel that could enable individuals with less leisure time to increase overall PA and behaviour. Also, wider benefits



could be achieved if the whole family is involved in PA especially when lack of time is a major issue.

In the current study, environment and religion had no significant associations with any of the studied variables. This is, despite the hot weather during data collection of this study in April/May, which was hypothesised as a potential barrier and reported elsewhere (Egan et al., 2013, Amin et al., 2011).

Moreover, to ensure construct validity of the scale, a common factor analysis method using Principle Component Analysis was performed. Results showed cross item contribution of items/questions within lack of willpower, time, energy and skills indicating mixed responses. Similarly inputs from questions on lack of social support and lack of skills and energy were interlinked (Analysis is presented in Appendix 4.8). However, using Cronbach alpha and McDonald's Omega coefficients was equal to 0.80 and 0.75 respectively indicating moderate reliability of the 27 items/questions scale (Dunn et al., 2014).

#### 4.5.6 Limitations of the study

Due to the cross-sectional nature of the study, the associations reported may not indicate causality. In addition, despite attempts to minimise possible types of bias before and within the implementation of this study, one must acknowledge potential errors and the possibility of a respondent bias (misclassification) that could have resulted from imprecise memory of past self-reported levels of PA, sitting time and barriers to PA (Trost and O'Neil, 2014).

Sitting time was assessed using a single question within the GPAQ. This may estimate long bouts of continuous sitting (e.g. screen viewing) but may not be adequate to estimate interrupted bouts of sitting time within work and/or travel domains (e.g. on transport, whilst shopping, meal duration etc) and thus may not be an accurate reflection of sitting behaviour in the Omani adults with T2D. Given the limited research on sitting time and sedentary behaviour in the Arabic world (where culture habits differ from western society) this behaviour merits further investigation using objective measurement tools if at all possible such as

accelerometers (Healy et al., 2011b). In addition, observational data on sitting habits may help to inform the validity of data collected.

Additionally, given that this study was carried out within clinical settings, participant may have attempted to respond inaccurately on their PA behaviours to be socially accepted to their health care providers indicating social desirability bias (Grimm P, 2010). Moreover, it is possible that interviewers' characteristics such as: a) gender [female participant may have been more comfortable discussing their PA behaviour and health status with female interviewer (Huddy et al., 1997)], b) work experience [compared to younger/less experienced interviewers, the older/more experienced staff may have gained more cooperation and trust from the participants (Blom and West, 2016)], and c) skills [participants may have responded differently to skilled interviewers who were nurses vs doctors (Blom and West, 2016, Davis et al., 2010)]. Future studies could usefully consider objective PA measurement tools and qualitative approaches to explore barriers to PA.

Moreover, PA questionnaires, namely GPAQ in this study, may have introduced measurement bias as they are less sensitive to quantifying low intensity daily activities that are reported to be the major activity in older and sub-populations (Clark, 1997). Validating GPAQ for this population using an objective measure would be useful for quantifying activity levels and ultimately designing appropriate PA promotional interventions.

Finally, future attempts to explore barriers to PA could equally include work and travel domains to cater for diversities in both PA behaviour and sedentary lifestyle across subgroups of adults with T2D. This may be helpful in planning for interventions to promote PA behaviour change across PA domains.

#### **4.6 Conclusions**

Overall, levels of PA were low across all activity domains and median sitting time was high. Females, older age, reporting 'in-active stages' of PA and

barriers to PA were negatively correlated with meeting PA recommendations. Given the significant association of meeting PA recommendations with gender, interventions to modify PA behaviours should be linked to gender-specific barriers to PA. Sitting time in older individuals with T2D was greater than regional and global estimates. PA consultations based on behaviour change techniques and which are specific to individual PA stages of change may be promising strategies to increasing PA behaviour and reduce sitting time.

In addition, this study identified lack of willpower, low resources and low social support (especially in females) as the most common barriers to performing leisure PA. The current findings can be used to inform the design of physical activity interventions for testing in clinical trials. The specific areas which might be usefully included to address barriers to performing PA are a) assessment of individuals' readiness to change b) low cost options for PA resources and social support c) approaches aimed at increasing individuals' understanding of what constitutes PA and d) methods that are flexible and tailored to the specific needs of subgroups of adults with T2D. In addition, approaches that enhance self-efficacy (and will power) and social support should be included.

## **Chapter 5 : Formative work (Qualitative sub-study): Health professionals' perceptions about physical activity promotion in diabetes care within primary health care settings in Oman**

### **5.1 Introduction:**

As outlined in chapter 2, section 2.2.1, diabetes management in Primary Health Care (PHC) in Oman is managed by a multi-disciplinary team of health professionals (HPs) namely doctors, nurses, dietitians, and health educators. Current Omani diabetes management guidelines (Ministry of Health Oman, 2015) recommend that PA is to be discussed with all patients, but the level of awareness and indeed implementation of these guidelines by health professionals (HPs) is unknown. Globally, evidence on PA promotion indicates that it remains an under-used component in diabetes care (Colberg, 2012). Only a small number of studies have reported any PA counselling by diabetes HPs and this appears to have been due to lack of time, confidence, knowledge, training, and resource to provide ongoing support (Matthews et al., 2014a, Mabry et al., 2014b, Jansink et al., 2010, Morrato et al., 2006, McKenna et al., 1998).

However, a number of methods of reinforcing PA promotion in diabetes primary care have been evaluated and shown to be effective and feasible (see Section 3.5.4) (Avery et al., 2015a, Connelly et al., 2013). PA interventions for adults with T2D can be delivered in a clinical or community practice context, and can be provided in various settings, by various professionals, using various modes of delivery (Matthews et al., 2014b). However, there is no consensus on what are the optimal PA intervention components. Significant improvements in glycaemic control are associated with interventions of longer duration (e.g. 6-12 months) (Avery et al., 2012), or where PA advice is combined with dietary advice (Umpierre et al., 2011). Furthermore, PA consultations linked to a

theoretical framework of behaviour change and tailored to the needs of individuals with T2D are more effective than more general PA advice (Matthews et al., 2014b).

In addition, pedometers have been widely reported as an effective follow up and monitoring tool to increase PA behaviour (Lubans et al., 2009). However, the majority of the research to date has been undertaken in controlled research environments, mainly in western countries (Avery et al., 2012). Little is known if these interventions work if undertaken in everyday practice, especially in Arabic speaking countries where culture, tradition and health care settings are distinct.

## **5.2 Objectives**

The current study aimed to determine the perceptions of HPs on PA promotion for adults with T2D within a local clinical primary care setting in Oman (Alghafri et al., 2017b) (see Appendix 5.1). Specifically, it aimed to explore the following objectives (with respect to PA promotion):

- The perceived barriers and opportunities.
- Who should be responsible for the delivery of PA interventions.
- The perceived intervention components that could possibly be implemented.
- The required resources/actions to integrate PA in diabetes care.

## **5.3 Methods**

### **5.3.1 Setting and conceptual framework**

Four focus group discussions (FGDs) were conducted in June - July 2015 to explore perceptions of HPs from different disciplines on possible PA

interventions within routine diabetes primary care. Planning a feasible PA intervention within a clinical setting requires the views of health care providers at different health care levels (Chakravarthy et al., 2002). Hence, this approach was guided by an ecological model of health behaviour (Sallis et al., 2006). Focus group discussions were chosen over in-depth interviews, because it was felt that the dynamic group interactions would allow more detailed insights within group disciplines (Virginia & Victoria, 2013).

This qualitative research is based on an interpretative phenomenological analysis (IPA) method of understanding a group's perception of a particular topic using purposeful sampling (Smith J, 2004).

### 5.3.2 Participants

Participants were recruited because they were healthcare professionals currently involved in the delivery of aspects of the diabetes care service in Oman. To ensure sufficient diversity of views, HPs involved in diabetes primary care from multiple disciplines (family physicians, dietitians, health educators, health managers and general practitioners) were recruited to the FGDs (participants of the same discipline in each group). The aim was to recruit between six and ten participants per focus group (Virginia & Victoria, 2013). Participants (doctors, dietitians, health educators, and nurses) in all health centres in the Muscat region were invited by written request by the Director of Primary Health Care in the Directorate of Health Services. The invitation letter was addressed to the head of each health centre to inform the potential participants about the date and venue of the FGDs and invite them to take part in the discussions. Subsequently, a list of staff who were willing to participate was sent to the Director of Primary Health Care and shared with the primary investigator (TSA) of the current study. An information sheet describing the study and summarizing the available evidence from Oman (Mabry et al., 2014b, Mabry et al., 2013, Mabry et al., 2012) was shared with the participants as part of their invitation letters. The information provided included evidence on low levels of PA and high prevalence of non-communicable diseases, particularly

diabetes, in the Omani population. This information was expected to encourage participation and build interest on the subject. Follow-up telephone calls were made to arrange a time and place for the interviews. Although Arabic was the mother tongue for all participants, all interviews were conducted in English, since it is the common working language in the health sector in Oman.

### 5.3.3 Methodological approach

All focus groups were organised in a conference room with a semi-circle sitting arrangement at a time and date convenient for the participants and researchers. All participants provided written informed consent (see Appendix 5.2). The focus groups, lasting 60-150 minutes, were led by a trained facilitator (TSA) and assistant facilitator (SA) and audio-recorded. The assistant facilitator took notes during the discussions and made sure the facilitator did not overlook any participants trying to add comments. Discussions continued until saturation of new information was reached. The discussions lasted approximately 100 to 120 minutes .

### 5.3.4 Topic guide

A semi-structured topic guide (**Error! Reference source not found.**) was developed which contained prompt questions aimed at eliciting participants' perceptions on the barriers and opportunities to promoting PA in diabetes care, and their suggestions on allocation of responsibilities, possible intervention components and required resources/actions (Virginia & Victoria, 2013). The topic guide was then reviewed by the research team, and pilot-tested in a mixed group of six health professionals (one doctor, one nurse, two health educators and two dietitians). Changes were made to ensure common understanding and dynamic discussion. Because the pilot FGD revealed that participants were not fully aware of the common PA terminologies for intervention methods, an explanatory summary diagram highlighting examples of PA delivery methods

(e.g. consultations and pedometers) was given to all participants before the start of each FGD (see Chapter 3, Figure 3.2).

**Figure 5.1: Topic guide**

	Questions
Opening	<p>To what extent does your work in the diabetes clinic involve addressing PA?</p> <p>How important do you think addressing PA is among the various health priorities in your routine diabetes clinic?</p>
Introductory	Who are the health professionals currently providing PA information to people with diabetes in PHC – if any? How and in what format?
Transition	<p>In relation to PA and T2D how comfortable are you with the following:</p> <p>Your confidence to discuss and assess PA with patients attending diabetes clinics</p> <p>Your ability to motivate and build self-confidence in patients for more PA</p> <p>Your ability to use behavior change techniques in patients for more PA</p> <p>Your willingness to endorse PA along with the other health professionals involved in diabetes care in PHC?</p>



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Key	<p>What are the</p> <p>Barriers to PA promotion in diabetes management in PHC?</p> <p>Opportunities to PA promotion in diabetes management in PHC?</p> <p>Who can best be responsible of PA promotion in the current primary diabetes care?</p> <p>Based on reflections from literature, what are your thoughts on the following physical activity delivery methods:</p> <p>Physical activity consultations</p> <p>Encouraging walking is one of the successful interventions for patients with diabetes, how can this be done?</p> <p>Using technology to promote PA in patients with T2D</p> <p>What could be useful components for an effective physical activity intervention in diabetes care?</p> <p>What resources/actions are needed to integrate PA in routine diabetes care in PHC?</p>
Ending	Is there anything else you would like to add?

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### 5.3.5 Analysis

Data obtained from the audio tapes were transcribed verbatim and then analysed using Nvivo 11 (QRS international, 2016). The approach used followed thematic content analysis (Virginia & Victoria, 2013) in line with the key aims of the study. Initial transcripts were read several times by authors TSA and SMA followed by open coding, grouping and categorizing data according to emerging themes. A coding scheme was then developed based on the major recurrent themes. Themes and sub-themes were cross-checked independently by two researchers (SA, and YA). The final themes and sub-themes were revised by a qualitative researcher (ZA) as a further measure of inter-rater reliability. Continuity of interpretation was ensured by one researcher (TSA), being responsible for the data collection and analysis. Transcripts were re-visited whenever conflicting interpretations of themes occurred.

### 5.3.6 *Ethics*

Prior to the commencement of each focus group, an explanation about the aim of the study was given along with details of what participation would entail. Participant were given the opportunity to ask questions and withdraw if felt uncomfortable at anytime. Written informed consent (in which participants' anonymity and confidentiality was assured) was provided by each participant. The study was approved by the Regional Research and Ethical Review Committee, Ministry of Health, Muscat, Oman (see Appendix 4.3).

## 5.4 Results

Twenty-nine HPs participated in the FGDs. All of them were involved in diabetes primary care across Oman. More than half (n=17/29) were doctors, of which three were additionally mid-level managers at central (ministerial), regional and departmental levels. The remaining participants were nurses (n=5/29) dietitians (n= 4/29) or health educators (n=3/29). The majority of the participants were females (n=20/29).

Mean (SD) years of work experience was 8 (4) (range = 5-21) years with family physicians having the most years of experience within the group. However, irrespective of experience participants expressed that: a) PA is a health priority in routine diabetes clinics, and b) their contribution to address PA was limited and ranged from unremarkable to providing simple and general PA advice. Current PA promotion in diabetes care was described as "inadequate", "inconsistent" and "unstructured". Participants in the manager group expressed "no confidence" to discuss and assess PA with patients attending diabetes clinics, nor the ability to motivate, build self-confidence or use behaviour change techniques in patients for more PA. Participants of other groups used variable terms such as "less", "not sure" and/or "somewhat sure" for the same. Nonetheless, all groups/ health care providers highlighted their uncertainties in addressing PA in diabetes care. However, all expressed strong willingness to

endorse PA along with the other health professionals involved in diabetes care in PHC.

#### 5.4.1 Barriers and opportunities to promote PA in diabetes primary care

Three recurring themes related to barriers and opportunities to addressing PA in diabetes care were identified: the health care system, individual/ intrapersonal (patient related) factors, and the environment/community.

##### *Health care system related barriers and opportunities to PA promotion*

#### **Barriers**

The main barriers identified across the groups were lack of PA supportive guidelines/standards, lack of resources including knowledge and skills for effective PA promotion, lack of facilities and overall limited space available for patient instruction as illustrated by the following quotes:

*“Lack or poorly communicated physical activity guidelines and physical activity standards from the central (ministerial) level to the clinical (practical) levels” GP 6*

*“Am not sure about my knowledge and skills to support physical activity in patients with diabetes who may have multiple comorbidities and require structured physical activity advice, not just a general statement” Dietitian 7*

*“We don’t have a private place to sit with the patient” Dietitian 1*

Other barriers that were cited included lack of educational materials, poor PA referrals, inadequate manpower, and diabetes clinics restricted to morning shifts (not convenient for patients with committed mornings jobs). It was also noted that contrary to other primary care programs in Oman, PA is not integrated in

the electronic primary health care information system limiting operationalization of PA services.

*“Physical activity is not considered in the primary health information system "ALSHIFA" which makes it difficult to prescribe, follow up or evaluate” Family Physician 5.*

### **Opportunities**

In terms of opportunities highlighted, HPs were highly motivated to undertake PA promotion in diabetes care and willing to share the responsibilities of promoting PA with colleagues and patients. Implementing potential PA interventions in the health centre or the community was considered feasible. Additionally, the family physician group suggested gathering data from patients through research on perceptions and barriers to PA in order to identify potentially effective PA interventions. The comments below illustrate these views:

*“Another thing which I believe in is the sharing, I really believe that we will not be able to do it alone, so we need everybody – and especially the patients – on-board” Family Physician 4*

*“We need more studies about perceptions and then about the barriers” Family Physician 6.*

*Individual/ interpersonal patient related barriers and opportunities to PA promotion*

### **Barriers**

Cultural norms of the acceptability of physical inactivity, sedentary jobs and use of domestic helpers were common barriers identified at the individual/ interpersonal level. Females were perceived to be more prone to inactivity due to the cultural and societal restrictions. Terms such as “lazy”, “not willing”, “not

motivated”, “no self-confidence” were used to describe inactive individuals as indicated in the following quotes:

*“In our culture (we don’t view physical activity as important?), taking medicine is enough, no need for physical activity” Family Physician 5*

*“Most of the Omani people are becoming sedentary at work” Dietitian 5*

*“Our main problem is with the females, whom, they don’t have the time, they don’t have the place to do it, and ...they have many social commitments” Manager 8*

### **Opportunities**

Participants stressed the importance of personalising PA interventions to patients as they may be at different levels of readiness to perform PA. Provision of the available social (family) support for PA was equally recommended by participants.

*“Patients’ readiness to carry out physical activity has to be evaluated” Dietitian 2*

*“We need to emphasise group, family and friends “social” support for physical activity, especially for the population in the diabetic clinic who are elderly” Manager 7*

*Environment/community related barriers and opportunities for PA promotion*

### **Barriers**

All participants perceived a lack of PA facilities, particularly safe walking areas. Yet it was felt that potential PA facilities within the community, in schools, are

under-utilized by the public. Hence, participants felt that other PA stakeholders (sectors) were not supporting the Ministry of Health in PA promotion or implementing opportunities effectively. Although hot weather was mentioned, opportunities for indoor activities and PA in the early morning were also discussed.

*“We can't utilize facilities in the community (school sports halls) for physical activities especially in the evening times when it's closed”*

*Manager 3*

*“The other sectors should cooperate with us” Manager 1*

*“Weather is a problem, but we can select a time where the weather is acceptable, like early mornings” Manager 3*

### **Opportunities**

The term “community mapping” was used by a senior manager who thought health workers should be aware of PA facilities within the geographical catchment areas of primary health care centres, in order to facilitate PA referrals when advised. Interestingly, available volunteering health groups were perceived to be underutilized for PA promotion compared to other primary health care programs.

*“Community mapping for physical activity facilities (places and volunteering buddies) to inform health care providers is a good idea to improve PA referrals” Manager 6*

*“The Ministry of Health has utilized an active group of volunteers from the community to promote maternal and child health programs*

*such as breastfeeding, I think we can utilize this group to promote physical activity too” GP 1*

#### 5.4.2 Allocation of responsibilities within diabetes primary care

There was no consensus on who should take the responsibility for PA for adults with diabetes in PHC. Interestingly, due to uncertainties towards how to deal with PA promotion in the presence of comorbidities, dietitians did not feel that it could be their responsibility. However, other HPs thought that PA responsibilities should be allocated to the dietitians, as combining dietary advice with PA was perceived as appropriate. In fact the dietitians and health educators group went on to suggest new recruits such as physiotherapists or trained PA nurses. Family physician doctors, on the other hand, suggested a team approach to promote PA in diabetes care, but since associating PHC services/programs to a focal point is the norm, they could then be the coordinators along with the dietitians to deliver PA services.

*“It is the dietitian’s role to promote physical activity to patients with diabetes” GP 1*

*“Physiotherapist or a trained physical activity nurse” Dietitian 3*

*“The entire team is responsible, but if we have to choose, I would say the doctor, “us”. Family Physician 1*

#### 5.4.3 Intervention components and required resources to address PA in diabetes primary care

Three main themes identified from a systematic review by Matthews et al. (2014b) were proposed for discussion: PA consultations (face to face, group or phone), PA sessions, and/or use of technology.

*PA consultations (face to face, group or phone)*

Consultations were the most desirable intervention component although HPs did not feel skilled to undertake this. However, due to participants' hesitancy on what to say, why, where and when, they all consistently recommended extensive training for the team involved in diabetes care.

Group consultations on the other hand were not welcomed in the current primary care setting due to associated complex arrangements (time, space, and logistics). Dietitians were the only group that recognised the potential use of pedometers, but the concept was generally welcomed by all

*“Physical activity consultation is one important part that we can integrate it in diabetes care” Family Physician 2*

*“It should be well-structured physical activity consultations. I think no one is well trained in this field” Family Physician 4*

*“I know that physical activity consultations linked to behaviour change is more effective, but we don't know how to do it” GP 4*

*“Some people like face to face physical activity consultations which I think is better as not everyone has access to telephones, and don't forget the cost of calling” Dietitian 4*

*“I believe in our Omani culture face to face physical activity consultations would be better than phone or group or any other*



*settings. People here like the patient-doctor interaction, especially in the initial visits” GP 6*

*“Group consultations are difficult to manage. I mean we need more space, time and other logistics” Dietitian 4*

#### *PA sessions*

Participants thought that arranging services to promote PA, mainly walking sessions, supervised by the health centre was a good idea (and a precedent had been set with previous self-help groups and campaigns). However, such activities were not encouraged within the campus of the health centre due to the lack of safe and appropriate places to walk. Walking (individually, accompanied by somebody or in a group) was the most common type of PA viewed as acceptable, and was encouraged by all groups irrespective of disease condition or individuals' age. Volunteers from the community were suggested by health educators in the dietitian group to be linked to patients with diabetes who are willing to walk but lack social support to undertake this. The manager group felt that aerobic, resistance or Zumba classes could be arranged by staff from health centres for patients in a private gym, however it may not be sustainable.

*“I don't feel bringing physical activity sessions to the health centre is a good idea. However, health educators may arrange and manage activities within the community” Family Physician 8*

*“We have these beautiful volunteers called the support group who are underutilised in PA promotion for diabetes care. We can use them to organise walkathons in the neighbourhoods or link them to walk patients. We also have the association like the elderly*

*association of woman and the Omani Women Association who can do something similar to anti-smoking activities” Dietitian 7*

*“I also think health centres can coordinate with nearby private facilities “the gym” for possible aerobic, Zumba or resistance exercises for interested young patients perhaps, but then sustainability may be an issue for a larger group of patients” Manager 8*

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### *Use of technology*

Participants felt unsure of the benefits of technology for older individuals and those with limited education. The use of tablet, and PA promotional websites were favoured for young patients who were more likely to be familiar with technology. Telephone applications and use of smart devices such as “watches/bracelets”, smart games such as Nintendo “Wii” consoles, and digital personal trainers were only mentioned by the family physician group, however cost was perceived as a drawback. Interestingly, use of a common telephone application “WhatsApp” to promote PA in diabetes care was commonly suggested:

*“Nowadays using WhatsApp is common [simple phone application], maybe we can introduce it to promote PA” Manager 6*

### *Required resources to promote PA for adults with type 2 diabetes*

The most repeated prerequisite by all groups was establishing a supportive environment for PA promotion in the PHC setting, namely structural changes, for example a consultation room, in order to provide privacy to patients. Additionally, clear and well communicated guidelines across health workers and PA stakeholders were highly recommended. Most importantly, accredited PA training for all health care professions involved in diabetes care would need to be embedded and/or medicalized within PHC continuous professional

development (CPD) training programs. Training for all was perceived as essential to overcome problems of staff shortages related to the uneven distribution of staff delivering primary diabetes care in health centres and their rapid turnover rate due to maternity leaves, retirement and transfers to other health centres. This was hoped to maintain and sustain service delivery for PA promotion.

Proposed training topics were variable including: PA definitions, guidelines, measurements, consultation skills including behaviour change techniques (goal setting and motivation), and follow up and monitoring tools.

*“Physical activity is not medicalized and hence there are no standard follow up, monitoring or evaluative tools for it in primary care” Family Physician 1*

*“Prepare a physical activity friendly environment in the health centre. For example encourage health care workers to move (active meetings), ensure private consultation rooms and everyone in the health centre should participate” GP 1*

## **5.5 Discussion**

The current qualitative study was undertaken to complement the findings of the quantitative study, to determine perceptions of implementing PA services in diabetes primary care. Consistent with ecological models of health behaviour (Sallis et al., 2006), the responses from the multidisciplinary groups of this study reflect perceptions of the multidimensional influences on PA and the necessity for multilevel actions to address them. Given the sparse evidence available on appropriate PA interventions for Arab populations, this study provides a framework for the design of an intervention to integrate PA in routine diabetes primary care that can be subsequently evaluated.

Three themes were identified: barriers related to the health care system, individual/ interpersonal factors, and the environment/community. In the current study HPs expressed concerns relating to inconsistent and outdated PA guidelines. The recent Omani diabetes management guidelines on PA are based on outdated evidence and therefore require revision as the last production was in 2015 (Ministry of Health Oman, 2015). Guidance on PA recommendations for adults with diabetes has been described in several studies (Norton et al., American Diabetes Association, 2010), however further details for implementation are required. Since it is a norm to have a representative body for health programs in Oman Ministry of Health, assigning one for implementing PA services would be ideal to execute PA guidelines (at least 150 minutes of moderate to vigorous physical activity or 75 minutes of vigorous PA/week or an equivalent combination of moderate- and vigorous-intensity PA achieving at least 600 MET-minutes per week (World Health Organization, 2010) across HPs involved in diabetes care. However, other constraints reported related to availability of consultation rooms, educational materials, manpower, timing of diabetes clinics, and integration of PA in the current health information system. These need to be developed and included in an executive PA promotion action plan.

At the individual/ interpersonal patient level, socio-cultural barriers, particularly the restrictions noted for women such as limited safe PA facilities and walking tracks, are reported from other Arab communities in the Middle East (Kalter-Leibovici et al., 2010) and the USA (Jaber et al., 2011, Amin et al., 2011). Hence, PA promotion should be targeted to address females' inactivity levels through widening available opportunities. This could include utilization of PA school programs (Horne and Tierney, 2012, Weiler et al., 2012), and widening the urban design regulations and infrastructure (Heath et al., 2012).

Perceived barriers which were related to the environment/community were similar to findings of other studies, namely hot weather and limited PA facilities (Ali et al., 2010). PA interventions should therefore consider walking tracks and

special culturally appropriate exercise facilities and services e.g. women only exercise classes (Horne and Tierney, 2012).

It was agreed that in an ideal health care setting all HPs should have the responsibility and skills to effectively deliver PA information. In fact PA endorsement by health workers in PHC settings is reported as one of the seven investments that work in promoting PA (Trost et al., 2014). Research suggests that patients consider their GP to be the most trusted source of PA advice (Schofield et al., 2005). However, despite mixed views on responsibilities for PA promotion, the tendency was for dietitians to be the favoured sources for both diet and PA promotion by study participants in the current local PHC setting. Patients with T2D have previously reported finding it easier to manage dietary changes when in combination with PA (Malpass et al., 2009).

Face to face consultations were valued over telephone and/ or group consultations by participants, especially for initial consultations. This could be justified by the cultural preferences to discuss health issues in private; especially that females in Arabic speaking countries including Oman, may not feel comfortable to discuss their weight, health and PA behaviour in group settings (Al-Shookri et al., 2011). Additionally telephone consultations may not be accepted given the time and cost associated with using phone services. However, since evidence showed that telephone counselling is an effective method of increasing levels of PA in women with T2D in Western countries, such as the USA (Plotnikoff et al., 2010b), it is wise to consider its application in future PA interventions. Furthermore, except for few short-term studies (Muntaner-Mas et al., 2017), evidence on the use of telephone applications including WhatsApp in PA promotional interventions is limited specifically in the Middle East.

While the current study identified barriers to PA promotion by HPs, another complimentary formative study showed that lack of willpower was the most frequently reported barrier to performing PA by patients with T2D (Alghafri et al., 2017a). Hence, the use of motivational tools such as pedometers was welcomed by all HPs in the current study. Pedometers have been shown to be

helpful in increasing PA levels and in improving metabolic parameters in patients with diabetes in several previous studies (De Greef et al., 2010, Bravata et al., 2007a). An advantage with pedometers is their ability to increase the motivation to be more active and less sedentary on a daily basis, therefore future PA interventions could usefully test pedometer use.

Furthermore, community participation was reported as a potential good opportunity to facilitate PA in diabetes care (Horne and Tierney, 2012). The effectiveness of community involvement in PA promotion has consistently shown positive outcomes (Al-Siyabi H, 2012, Garrett et al., 2011). Referrals to an organized community PA resource, such as walking buddies (community volunteers), and neighbourhood gym may all be adopted within primary health care providers.

Finally, irrespective of who the PA focal point is in PHC, intensive training for health care providers on PA is required including benefits, definitions, recommendations, type, measurements, dealing with multiple comorbidities and evaluation. To ensure sustainability, training workshops were advised within primary health care CPD activities. More importantly, behaviour change training was highly recommended. A PA training package was reported to be feasible within primary care setting in UK (Avery et al., 2016). However, similar attempts need to be evaluated in Oman.

## **5.6 Study limitations**

It should be noted that the facilitator (TSA) had worked with all study participants for several years, and thus, familiarity with all participants and work experience may have introduced bias, with participants providing socially desirable responses (Grimm P, 2010). Additionally, some questions (order of the questions) may have been biased and influenced respondents' answers as responses on the barriers to PA may have influenced the later discussions on the possible interventions (Galdas, 2017, Virginia & Victoria, 2013). In addition, the study participants were introduced to examples of PA interventions from the

literature search and this may have triggered them to give structured responses that could have been more exploratory if they were unprompted (Virginia & Victoria, 2013).

Moreover, it is not possible to assess how representative the views reported in this study are of those of the wider population of HPs working in diabetes care within PHC across the different regions of Oman (sample bias). All participants have a very good working knowledge of English, but their responses may have been limited since the interviews were not conducted in their mother tongue, Arabic. Another potential limitation is that sitting time and sedentary behaviour were not included as specific topics for discussion within the focus groups. Prolonged sitting time has been identified as an independent risk factor for diabetes, cardiovascular disease, and all-cause mortality (Wilmot et al., 2012a). Hence, further studies are required to explore HCPs perceptions on improving sitting time and sedentary behaviour in adults with T2D in Oman. Additionally, although insights from adults with T2D about appropriate PA methods in diabetes care were explored in chapter 4 (see Section **Error! Reference source not found.**), in-depth qualitative approach may be required to compare the results with findings from the current study.

## 5.7 Conclusion

This study highlighted primary care HPs' perceived barriers and opportunities for a PA program for patients with T2D. Despite identification of clinical, individual, and environmental factors that could limit PA behaviour, opportunities do exist within the positive spirit of health care workers for PA promotion. This study proposed an intervention with multiple components across clinical and community contexts. In the presence of various diabetes primary care providers, dietitians were considered best to provide face to face PA consultations linked to behaviour change techniques. Participants were excited to introduce the common technology based tools to support PA including phone applications "WhatsApp" and pedometers within diabetes

primary care. Additional community support was recommended from the current available resources (volunteers/ PA facilities). To initiate and sustain PA promotion, a training program needs to be institutionalized within the current CPD activities for all health care providers in primary care.



## **Chapter 6 : Study Protocol for “MOVEdiabetes”: A Trial to Promote Physical Activity for Adults with Type 2 Diabetes in Primary Health Care in Oman**

### **6.1 Introduction**

The evidence around the impact of PA on both the prevention and management of T2D is well documented (see Section 3.2) (American Diabetes Association, 2010, Di Loreto et al., 2005). To achieve the clinical benefits of PA, the WHO recommends at least 150 minutes of moderate-intensity PA OR 75 minutes of vigorous-intensity PA per week, which equates to an equivalent combination of moderate- and vigorous-intensity PA achieving at least 600 MET.min/week (World Health Organization, 2018b).

Evidence from the literature search in Chapter 3 (see Section 3.6) on the best PA interventions for patients with T2D in primary care worldwide was inconclusive. Interventions differed by settings (primary care vs community), methods (consultations vs exercise sessions), and duration (short-term vs long-term). PA consultations and exercise sessions linked to theories of behaviour change seem to significantly improve activity levels for patients with T2D (Avery et al., 2016, Matthews et al., 2014b). Additionally, technology bound interventions and the use of motivational tools, such as pedometers, have been consistently recommended in interventional studies (Connelly et al., 2013, Bravata et al., 2007b). Walking interventions have also shown significant positive effects in lowering glycated haemoglobin levels (HbA1c) and improved diabetes health outcomes (Yates et al., 2013, Bird et al., 2013). However, there is still a gap in the evidence on the best methods, intervention components and intervention intensity that would be most effective in increasing long-term PA in the primary care setting for persons with T2D (Matthews et al., 2014b, Sanchez et al., 2015). Notably, almost all interventions have been carried out in non-Arabic speaking countries hence, exploring uncertainties about translating

existing evidence from western settings to local clinical settings in Oman whilst taking account of cultural boundaries is warranted.

Based on the findings from the literature search and series of studies presented in chapters 4 and 5, and given the time and budget allocated for this thesis project, a randomised controlled trial was developed, implemented and evaluated. This chapter reflects the protocol published in the *BMC Public health* (Alghafri et al., 2017d) (see Appendix 6.1) and thus additional elaboration is provided in the subsequent chapters.

## **6.2 Objectives**

### **6.2.1 Primary objective**

The primary objective was to evaluate the impact of a multi-component intervention (MOVEdiabetes) which aimed to achieve 150 minutes of moderate to vigorous physical activity/week ( $\geq 600$  MET.mins/week) in inactive adults with T2D attending primary health care facilities in Oman.

### **6.2.2 Secondary objectives**

The secondary objectives of the study were:

- Estimate the impact of “MOVEdiabetes” programme on cardio-metabolic risk factors.
- To evaluate the impact of utilizing a common telephone application, WhatsApp, as an intervention reminder and follow up tool.
- To examine the acceptability of the intervention (content, delivery and aims) to the participants and project officers (health care providers).

- To assess the practical issues (including costs) that could challenge or assist programme delivery and roll out.

### **6.3 Methods**

#### **6.3.1 Study design**

The study was a 1 year 1:1 cluster randomized controlled trial of the “MOVEdiabetes” intervention versus usual care. A cluster randomization design was used to minimize between group contamination by having the two groups (intervention and comparison) from independent health centres.

#### **6.3.2 Randomisation**

Group allocation was generated using a random numbers table generated in SPSS v21 by an independent statistician in Oman Ministry of Health. Out of 26 primary health care centres in Muscat, the capital of Oman, eight of them were randomly selected for this study to complete the required sample size. The selected health centres were randomised to deliver either the intervention (n=4) or usual care (n=4). Health centres were informed of their allocation verbally by the project investigator and will received an envelope containing invitation letter and project materials.

#### **6.3.3 Population**

To ensure that intervention delivery is embedded within routine diabetes care in the selected health centres, three project officers (POs) were recruited at each side (n=24) from existing health care providers (doctors/nurses/dietitians/health educators). Project officers received study specific training on the recruitment procedures, screening the participants, recording outcome measurements, and delivering the “MOVEdiabetes” intervention in intervention health centres (IHC).

All eligible patients attending their routine diabetes clinics in the selected health centres were informed about the study by the POs and invited to participate in the study. Interested patients were screened for physical inactivity using the Scottish Physical Activity Screening Questionnaire (Scot-PASQ) (NHS Health Scotland, 2013) (see Appendix 7.4).

*Inclusion criteria*

- Adults aged 18-60 years
- Diagnosed with type 2 diabetes
- Attending health centres for at least six months previously for diabetes care
- Assessed by project officer as having inactive behaviour
- No contraindication to physical activity
- Able to speak and read Arabic
- Willing and able to provide written informed consent to the study

*Exclusion criteria*

Patients with:

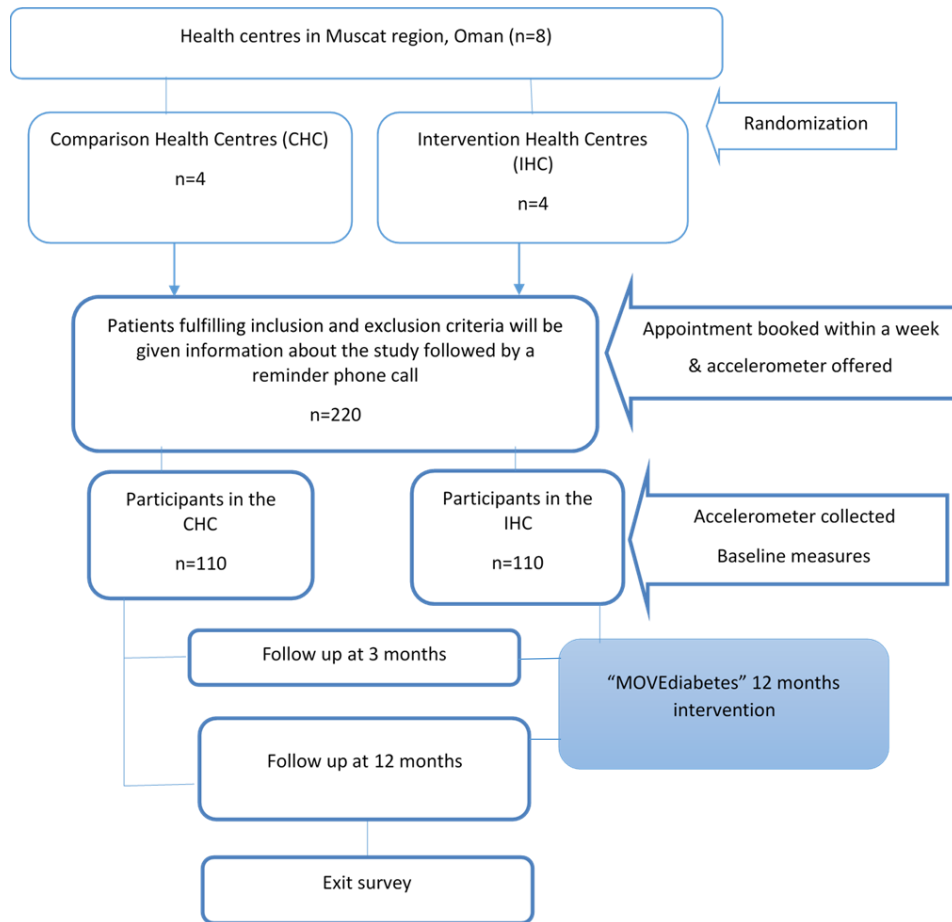
- Type 1 diabetes
- A history of myocardial infarction in the previous 6 months
- A serum creatinine >140 mmol/L (from previous recorded readings in the electronic health information system)
- Diabetic foot ulcers or at high risk of ulcer (severe peripheral neuropathy)
- Repeated hypoglycaemia or severe hypoglycaemia in previous 12 months

- No internet access for WhatsApp
- Physical activity > 150 minutes per week

#### 6.3.4 Recruitment

Recruitment took place over a 2 month period (May-June 2016). Inactive patients fulfilling the inclusion criteria were provided with a participant information sheet about the study by the POs. Due to budget constraints and uncertainties on cultural acceptance, a subset of eligible participants (40%) showing interest were offered an accelerometer to be worn for 24 hours a week (see Appendix 6.2) prior to their measurement visits as a primary measurement tool to step counts and sitting time. Initially all participants (n=220) were offered accelerometers until the required numbers were reached in all eight health centre. Subsequently, an appointment was given to all potential participants to attend a wellbeing clinic for baseline measures, linked to their diabetes clinic, within a week. A telephone call was made to all willing participants to remind them of their appointment and ensure activation of the accelerometer.

At the baseline visit the POs requested for written informed consent and logged any eligible individuals who declined participation (**Error! Reference source not found.**).



**Figure 6.1: MOVEdiabetes recruitment diagram**

Recruitment was monitored fortnightly and efforts to reduce loss to follow-up were made. Participants not attending their appointment were called to consider rescheduling their appointments. Reasonable travel costs for participants were reimbursed.

### 6.3.5 Ethics

Ethical approval was obtained from the Omani Research and Ethical Review and Approve Committee in the Ministry of Health and reciprocally approved in the University of Dundee (see Appendix 6.3). After explaining the participants' study information sheets (see Appendix 6.4 and 6.5), willing and eligible participants gave informed consent (see Appendix 6.6 and 6.7). All the individuals in both the study groups were given the right to withdraw consent for

participation in any aspect of this trial at any time without affecting their routine diabetes care. All participants were advised to report any serious adverse events occurring throughout the trial as they would immediately be referred by the POs to their general practitioner (Alghafri et al., 2017d).

#### 6.4 Measures/assessment instruments

Baseline and follow-up data were collected face to face and from the electronic health information system (HIS) in the health centre (AlShifa system) (Table 6.1).

**Table 6.1: Outcome measures**

	Tool	When	
Primary Outcome		Intervention	Comparison
GPAQ-MET-mins/week	Questionnaire	B, 3F, 12F	B, 3F, 12F
Accelerometer (activePAL™)	Reporting step count, MET-min/week, and sitting time	B, 3F, 12F	B, 3F, 12F
Pedometer  (YAMAX Digi-walker SW-200)	Reporting step counts	B, 3F, 12F	-
Secondary Outcomes			
Socio-demographic data	Questionnaire	B	B
Height (m)	Stadiometer	B	B
Body weight (Kg)	Calibrated scales	B, 3F, 12F	B, 3F, 12F
Waist circumference (cm)	Tape measure	B, 3F, 12F	B, 3F, 12F
Lipid profile (mmol/l)	Blood test  (venous fasted sample)	B, 3F, 12F	B, 3F, 12F
Blood pressure (mmHg)	Sphygmomanometer	B, 3F, 12F	B, 3F, 12F

*HbA1c (%)	Blood test	B, 3F, 12F	B, 3F, 12F
	(fasted sample)		
Self-assessed general health	Questionnaire	B, 3F, 12F	B, 3F, 12F
Self-efficacy for PA	Questionnaire	B, 3F, 12F	B, 3F, 12F
Social support for exercise	Questionnaire	B, 3F, 12F	B, 3F, 12F
Cost analysis (description)	Detailed cost description	12F	-
Exit survey	Questionnaire (participants and project officers)	12F	-

(B=baseline; 3F= 3 month follow-up, 12F= 12 month follow-up)

\* while blood collection for HbA1c at 12month is mandatory, it was only done at baseline and 3 month if missing from the electronic health information system or recorded within more than 4 months prior to the measurement visits

## 6.5 Intervention

The intervention group received the “MOVEdiabetes” personalised PA consultations, pedometer (YAMAX Digi-walker SW-200) to measure weekly step counts and WhatsApp messages (Table 6.2).

**Table 6.2: MOVEdiabetes intervention components**

Intervention visits	Weeks													
	0*	4	8*	12	16	20	24	28	32	36	40	44	48	
Face to face physical activity consultations	x	x	x											
Weekly WhatsApp step count	x	x	x										x	
Monthly WhatsApp messages	x	x	x	x	x	x	x	x	x	x	x	x	x	

\*After 7days of PA recordings from accelerometers in the selected sub groups



### 6.5.1 Face to face PA consultations:

Recruited participants were offered individual consultations (maximum 20 minutes) by the trained dietitians on 3 occasions (0, 4 and 8 weeks) (Table 6.2). Notably, the accelerometer group were called to come to their respected health centres one week prior to their consultation to apply the programmed accelerometer devices. The protocol for accelerometer use is described in Appendix 6.2).

The consultations aimed to encourage participants towards achieving 150 minutes of PA per week ( $\geq 600\text{MET-mins/week}$ ) at 12 months which has been demonstrated to be clinically effective in diabetes management. It is estimated that a step count of not less than 6000-7000 per day is required to achieve this goal (Tudor-Locke et al., 2004). Participants were encouraged to increase their step counts gradually to achieve this goal.

Using a PA programme design based on a theory and the behaviour change techniques is widely proven to be effective (Avery et al., 2015a, Avery et al., 2012). The theoretical frameworks underpinning the intervention in this study were multiple including the Health Belief Model (HBM), the trans-theoretical Model (TTM) and the Social Cognitive Theory (SCT) (American Diabetes Association, 2010). These theories were based on existing evidence from the literature search and their practicality within clinical setting (see Section 3.5.5). The dynamic constructs of these theories, such as: a) self-efficacy (in the HBM and SCT), b) barrier identification and readiness to change (in the TTM), c) and social support for PA (in the SCT), were all hoped to interact effectively towards positive PA behaviour.

The “MOVEdiabetes” personalised, multiple contact, intervention programme utilised several behaviour change techniques based on the Abraham and Michie taxonomy (Abraham and Michie, 2008) which included (a) goal-setting for PA; (b) self-monitoring to achieve these goals; (c) frequent contact to provide accountability and sustain focus; (d) use of problem-solving to address goals and potential barriers to achieving them; (e) emphasis on managing

individual high-risk situations, and (f) information on what, when and where to perform PA.

#### 6.5.2 Self-monitoring of step count:

Participants were given a pedometer (YAMAX Digi-walker SW-200) at their baseline visit in order for them to be able to self-monitor their step count. Instructions on how to use the pedometer, how to record their daily steps and how to set daily step goals was discussed with the POs. Participants were asked to set individual goals and fill in a daily step count to be submitted to the POs in their respective health centres at 3 and 12 months follow up (see Appendix 6.8) and share their step counts through WhatsApp phone application.

#### 6.5.3 WhatsApp:

Participants receiving the intervention were asked to open and share a telephone WhatsApp application with the POs in their health centre to facilitate the reporting of their step counts and get support during the intervention period. Additionally, monthly standardised PA motivational messages, coinciding with international occasions, were delivered through WhatsApp telephone application (**Error! Reference source not found.**). The messages were initially prepared in English and then translated to Arabic language to be sent to the participants. The content was reviewed and approved by the central and regional research ethical committees (see Appendix 6.9).

Participants were also invited to join a WhatsApp peer support group to share their experiences with other “MOVEdiabetes” participants.

**Table 6.3: Content WhatsApp monthly messages**

Month	Message	Special occasion if any
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May	It is evident that regular physical activity of at least 150 minutes of moderate to vigorous intensity per week improves your body hemodynamics and blood glucose. Let's start slowly and build up the amount of time and intensity of the activity.	World hypertension day
June	Ramadhan is the month to fast from food and increase body movement, take this opportunity to increase your PA behaviour.	Ramadhan
July	Include physical activity in your happy social and religious events.	'Eid Al-fitter
August	Breast feeding is good for mother and her baby especially if it's complemented with health lifestyle including physical activity.	World Breast feeding week
September	Pilgrim is the event that include extensive physical activity. Increase your steps and keep on walking.	Eid Al-adha
October	Physical activity is good for prevention and management of cancer so try to reach to 10,000 steps a day.	Breast cancer awareness day
November	Celebrate the national day and have better diabetes control by increasing your daily walking steps.	Oman national day & World diabetes day
December	Aging is an unavoidable risk factor, prevent disability by increasing you physical activity.	International day of persons with disability
January	Start your new year with an aim to increase physical activity.	New year
February	Being active physically is an important part of good health. 20-30 minutes of moderate to vigorous PA a day can help improve your health.	Health lifestyle awareness day
March	Culturally, women are more vulnerable to be physically inactive. Keep moving to stay healthy, strong and pretty.	International Women's day
April	It's never too late to start being physically active.	World health day
May	Being active supports diabetes prevention and management.	Ramadhan

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## 6.6 Process evaluation

### 6.6.1 Programme acceptability

Programme acceptability explored post-intervention via brief exit questionnaires with all the POs and participants in the intervention health centres. The questionnaires aimed to explore the extent initial expectations and motivations regarding the programme were met, engagement with the programme, acceptability (content, delivery and aims) of the approach e.g. if the intervention was tailored to be appropriate and realistic to the individual's lifestyle, and elements of overall rating of the project including factors influencing willingness and ability to comply with the programme advice.

### 6.6.2 Fidelity to protocol

To ensure that the study is carried out with minimum interruptions and logistical constraints, several managerial steps were planned and agreed upon between the principal PI (TSA) and the POs. Additionally fidelity to intervention delivery was planned to be conducted through bespoke check lists and exit surveys (discussed in later in Section 9.2.1).

#### *Managerial:*

- The project group had monthly meetings to discuss issues regarding the PA consultations, and measurements to ensure their compliance to intervention protocol.
- A telephone application (WhatsApp) was used throughout the study period by project officers and the PI to manage the daily logistics and administrative queries.
- Attendance sheets were reviewed and discussed.

*Qualitative assessment:*

- Cross checking of 10% of PA consultation notes randomly selected by a recruited external assessor.

*Evaluative assessment:*

- The brief exit survey included questions (open ended) on adherence to the protocol specifically for project officers.

**6.7 Sample size**

To demonstrate a 50% between group difference in PA levels (MET-mins/week) over 12 months, to be detected at a power of 80%, and significance level of 5%, 128 participants were required to complete the study (64 in each arm). Based on a drop-out rate of 20%, 154 participants required to be recruited (77 in each arm). Assuming a recruitment rate of 70%, 220 potential eligible participants needed to be approached.

**6.8 Statistical analysis**

The initial quantitative analysis was an intention-to-treat analysis between the two cluster groups (intervention versus control) but secondary analyses were planned to explore the effect of actual treatment received. The initial analysis involved standard two-sample comparisons (parametric or nonparametric as dictated by the distribution of the data) looking at effect sizes at 3 and 12 months using t-tests or Mann-Whitney tests for differences in means as well as repeated measures or chi squared tests for differences in proportions. Differences by health centre were explored and entered in a regression models if statistically significant. The balance of characteristics between treatment and control arms were tabulated and differences were noted in linear regression models.

Results from the open-ended questions in the exit survey were analysed thematically to identify the perceived acceptability of the intervention (content, delivery and aims) to the participants and POs (health care providers).

## **6.9 Discussion/Rationale for current trial**

Based on population characteristics from the formative work, patients had multiple comorbidities and the majority did not meet the WHO PA recommendations (Alghafri et al., 2017c, Alghafri et al., 2017a, Alghafri et al., 2017b). Findings from chapters 4 to 9 were supportive for behaviour change programmes namely personalised face to face PA consultations and use of pedometers and phone applications (WhatsApp in this study) as follow up and monitoring tool.

To reduce the anticipated work load on staff and any extra patients' visits to the clinics, it was decided that the consultations should take place every 4 weeks in the first 3 months soon after training the dietitians (viewed as most appropriate to deliver the consultations on PA consultation techniques) was completed. The frequency of the consultations was linked to the participants' routine mid-year or annual diabetes evaluations. This approach was hoped to facilitate the integration of PA within the routine diabetes primary services.

Due to its popularity in Oman, the use of the WhatsApp phone application was highly recommended and was thought to facilitate the reporting and feedback system between the participants and their POs/peers.

Notably, findings from chapter 4 and 6 highlighted the importance of walking as the preferred PA to both the participants and HPs. For this, pedometers were introduced for self-monitoring and support for PA.

Despite positive discussions on group settings and community resources presented in chapter 6, it was not possible to include those within the "MOVEdiabetes" study due to limitations in time and resources.

## **6.10 Conclusion**

A multi-component PA methodology consisting of PA personalised PA consultations, and walking supporters (pedometers and use of phone application may be promising to promote PA in diabetes care. It was hoped that results from this study will enhance the evidence base for effective routes to increasing PA in inactive adults with T2D; by assessing the impact of “MOVEdiabetes” intervention on PA levels; providing a platform (feasibility evidence) for the “MOVEdiabetes” intervention to be initiated in routine primary care clinics; increase understanding of participant engagement, barriers, and opportunities; related to intervention procedures in this clinical and cultural setting.

## **Chapter 7 : Primary and secondary outcomes of the “MOVEdiabetes” study**

### **7.1 Introduction**

Consistent with the socio-ecological model of health behaviour (Sallis et al., 2006), and the Behavioural Change Wheel (BCW) (Michie et al., 2011a), the work presented in this chapter is underpinned by a series of formative studies undertaken in adults with T2D and diabetes primary care providers in Oman (presented in chapters 4 and 5) (Alghafri et al., 2017a, Alghafri et al., 2017b, Alghafri et al., 2017c). Results showed that face to face PA consultations linked to BCTs, devices to support walking (pedometers), and use of a telephone application (WhatsApp) could be promising components in an intervention design. Hence, these methods have been used in the “MOVEdiabetes” intervention for which the study protocol is presented in chapter 6 by Alghafri et al. (2017d) (see Appendix 6.1).

### **7.2 Objectives**

- To describe the effectiveness of the multicomponent “MOVEdiabetes” intervention on change in PA levels, (primary outcome) and changes in objectively measured steps/day, sitting time (hours/day), weight, BMI, HbA1c, blood pressure and lipids (secondary outcomes).
- To evaluate the impact of the “MOVEdiabetes” study on the self-perceived general wellbeing (perceived general health, sleep, mental health, pain and QOL) and associations between changes in the wellbeing measures with the primary “MOVEdiabetes” outcome is explored.
- To describe the cost of the intervention.



Most of the results presented in this chapter has been published in the *BMJ open diabetes research and care* (Alghafri et al., 2018) (see Appendix 7.1).

### 7.3 Methods

#### 7.3.1 Study design and randomisation

The study was a 1 year (April 2016 to June 2017) 1:1 cluster randomized controlled trial of the “MOVEdiabetes” intervention versus usual care. The director general of the directorate general of health services in Muscat region was informed and approached to officially approve health centres’ recruitment and randomisation procedures. Out of the 26 health centres in Muscat region, eight health centres were randomly selected and randomised using random number tables generated in SPSS v21 (see section 6.3.2) to deliver either the intervention (n=4) or usual care (n=4). Heads of the selected health centres were then sought for their approval to participate and informed on the study procedures.

#### 7.3.2 Sample size

To demonstrate a 50% between group difference in PA levels (MET-mins/week) over 12 months, to be detected at a power of 80%, and significance level of 5%, 128 participants were required to complete the study (64 in each arm).

Notably, the assumption of 50% between group difference was calculated based on the findings from an earlier study where estimation of SD of mean PA levels of 145 MET.min/week and sitting time of 0.2 (hours/day) (Alghafri et al., 2017d) indicating extremely low levels of PA and longer sitting time.

Additionally, given the limited literature, specifically relevant to the Omani population, this decision was viewed by the investigating team as appropriate on the grounds of cultural skewness towards low PA behaviour. Moreover, given the nature of having multiple components intervention design, the

investigation team trusted the likelihood that patients would participate as per the calculation above.

Hence, it was estimated that the study should detect a difference in the primary outcome (a between intervention and comparison patients difference) of 113.5 MET.min/week at 24 month follow-up with an intra-class correlation coefficient (ICC) of 0.1 (Masood and Reidpath, 2016).

Based on a drop-out rate of 20%, 154 patients were needed to participate (77 in each arm). Assuming a recruitment rate of 70% and a retention rate of 80%, 220 potential eligible participants would need to be approached (Alghafri et al., 2017d).

### 7.3.3 *Training*

Initially, three POs were recruited at each site (n=24) from the existing diabetes health care providers (doctors/nurses/dietitians/health educators). POs received a five day bespoke training programme facilitated by a Health Psychologist & Public Health Specialist from the UK and local PA experts. The training included recruitment procedures, outcome measurements, and delivering the “MOVEdiabetes” intervention including PA consultations (Alghafri et al., 2017d). The agenda for the training is included in Appendix 7.2.

It was then agreed by all the POs, that the dietitians would conduct the PA consultations (Alghafri et al., 2017b). This decision was based insights from health care professionals, reported in the formative studies (see Section 5.4.2).

### 7.3.4 *Measures/assessment instruments*

A multi-component questionnaire was developed, reviewed and approved by the research group and ethics committee (see Appendix 7.3). Except for the socio-demographic data at baseline and general wellbeing at baseline and 12 months, all primary and secondary outcome data were collected at baseline, three and 12 months (Alghafri et al., 2017d). The questionnaire included:

### *Socio-demographic data*

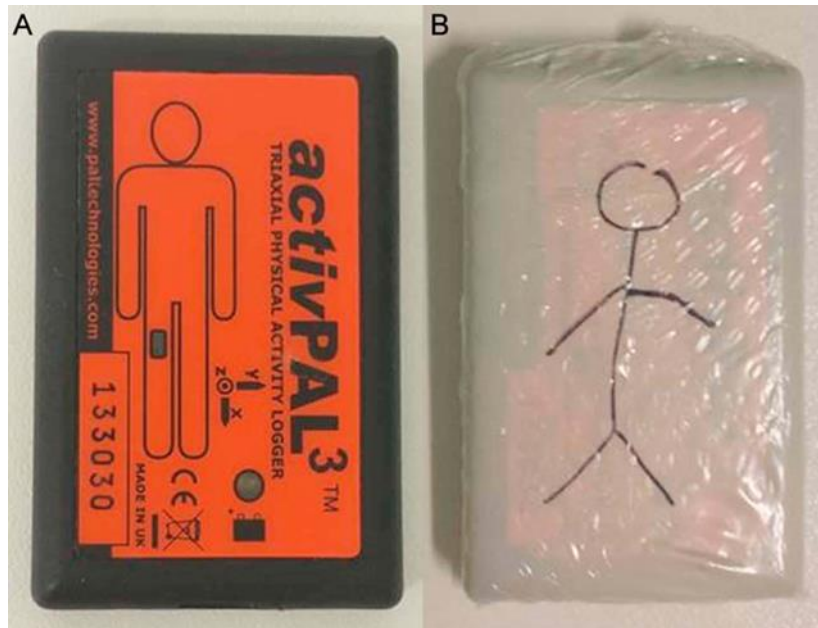
Age, gender, marital status, education, and income were collected from the electronic health information system (HIS) and if missing, the POs asked the participant for the information along with other components of the trial questionnaire.

### *Metabolic and cardiovascular biomarkers*

Weight, height, BMI ( $\text{kg/m}^2$ ), systolic and diastolic blood pressure (mmHg), HbA1c (%), and lipid profile (mmol/L) [total cholesterol, HDL, LDL, TGs] were collected from the HIS in the health centre.

### *Levels of physical activity and sitting time*

Self-perceived PA (MET.min/week) was estimated via face to face interviews using the Global Physical Activity Questionnaire (GPAQ) (Bull et al., 2009). GPAQ is a 13 item PA questionnaire where levels of PA (MET.min/week) are estimated across work, travel and leisure domains (World Health Organization, 2014b). Moreover, objective assessment of PA (steps/day) and sitting time (hours/day) was carried out in a sub-set of the eligible subjects (40%) who consented to undertake the accelerometer measurements (as per protocol). Initially all participant were offered accelerometers (activPAL™ micro, a ~20 grams professional PA monitor) until the required numbers were reached (Wilmot et al., 2011). Application and removal of the accelerometers was performed in the health centres by the POs. The devices were programmed to continuously work for seven days. They were wrapped in a plastic sleeve and then attached directly on the skin of the midline of the anterior aspect of the right participants' thigh using an adhesive pad and tube bandages to keep the activity monitor in place (Dowd et al., 2012) (Image 7.1). Participants were asked to record their sleeping/waking time and removal times in a daily log. Participants were advised not to remove the device unless for swimming or an allergic reactions, and to contact the POs in their health centre in these cases.



**Image 7.1: ActivPAL accelerometer device**

*The general well-being questionnaire (see Appendix 7.4)*

To assess the effectiveness of the “MOVEdiabetes” intervention on general health, sleep, mental health, pain, and quality of life, a 13 item English to Arabic translated questionnaire was used (a modified version from the short SF-20 questionnaire) (Rand health, 2015). The translation process followed the standard guidelines for the forward and backward translation of measurement tools recommended by the WHO (World Health Organization, 2017). Two of the researchers from the investigating team translated the English questionnaire into Arabic. Then, a third researcher back-translated the items from Arabic to English. Later, the questionnaire was submitted to a professional medical translation company (Al-Maani) to evaluate the equivalency of the meaning between the two versions, identify differences and agree the final wording.

Due to the complexity of the questionnaire, amendments were made to achieve maximum precision while translating the questionnaire. Because this study was conducted in daily routine diabetes setting, the questionnaire was shortened (13 out of 20 questions) to focus on key healthcare topics considering cultural appropriateness.

Participants were interviewed by the POs and asked to respond to the 13 items by ranking their perceptions of their general health (1 item), sleep (1 item), mental health (3 items), and pain (1 item). The mental health domains covered perceptions of calm/ peaceful, energetic, and downhearted or depressed moods. Additionally, quality of life (QOL) was estimated from responses to questions related to how the participants' general, physical and emotional health impacted their physical, work and social activities (7 items). Except for responses to two questions that had a selection of three choices, all other questions had five.

### 7.3.5 Piloting

A nurse from the POs team was recruited to carry out the piloting of the questionnaire. Piloting aimed to evaluate strengths and weaknesses of the questionnaire, identify any practical scientific issues and logistic constraints, before the full study commenced. The questionnaire was piloted with 10 participants (adults with T2D from a randomly selected health centre in Muscat region). No major changes were undertaken after the piloting. On reaching saturation (no new information) after 10 participants, no further piloting and amendments were undertaken. Although not formally assessed, the final questionnaire covered the objectives it purported to measure.

For the general well-being questionnaire, a factor analysis<sup>1</sup> (Tobias and Carlson, 1969) revealed adequate construct validity<sup>2</sup> (Cronbach and Meehl,

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<sup>1</sup> A statistical method used to describe the variability among observed, correlated data from items in a questionnaire. It is used for data reduction, and grouping based of item loadings (associations) on underlying factors.

<sup>2</sup> Defined as the degree to which a test measures what it claims to be measuring.

1955) of the items in the questionnaire and the Cronbach alpha value<sup>1</sup> was 0.80 indicating good internal consistency of the questionnaire (Cronbach, 1951).

### 7.3.6 *Blinding*

Except for the socio-demographic data at baseline, measures for the primary and secondary outcomes were collected by trained diabetes nurses who were blinded from the study objectives and group allocation. Owing to the nature of this study, the POs could not be blinded from study objectives, however they were not involved in data entry and/or analysis.

### 7.3.7 *The “MOVEdiabetes” intervention group*

#### *The PA consultations*

It was agreed by the POs to create specific branding for the “MOVEdiabetes” study and the logo (see below) was designed and displayed in the consultation rooms within the intervention health centres and all study materials (Image 7.2).



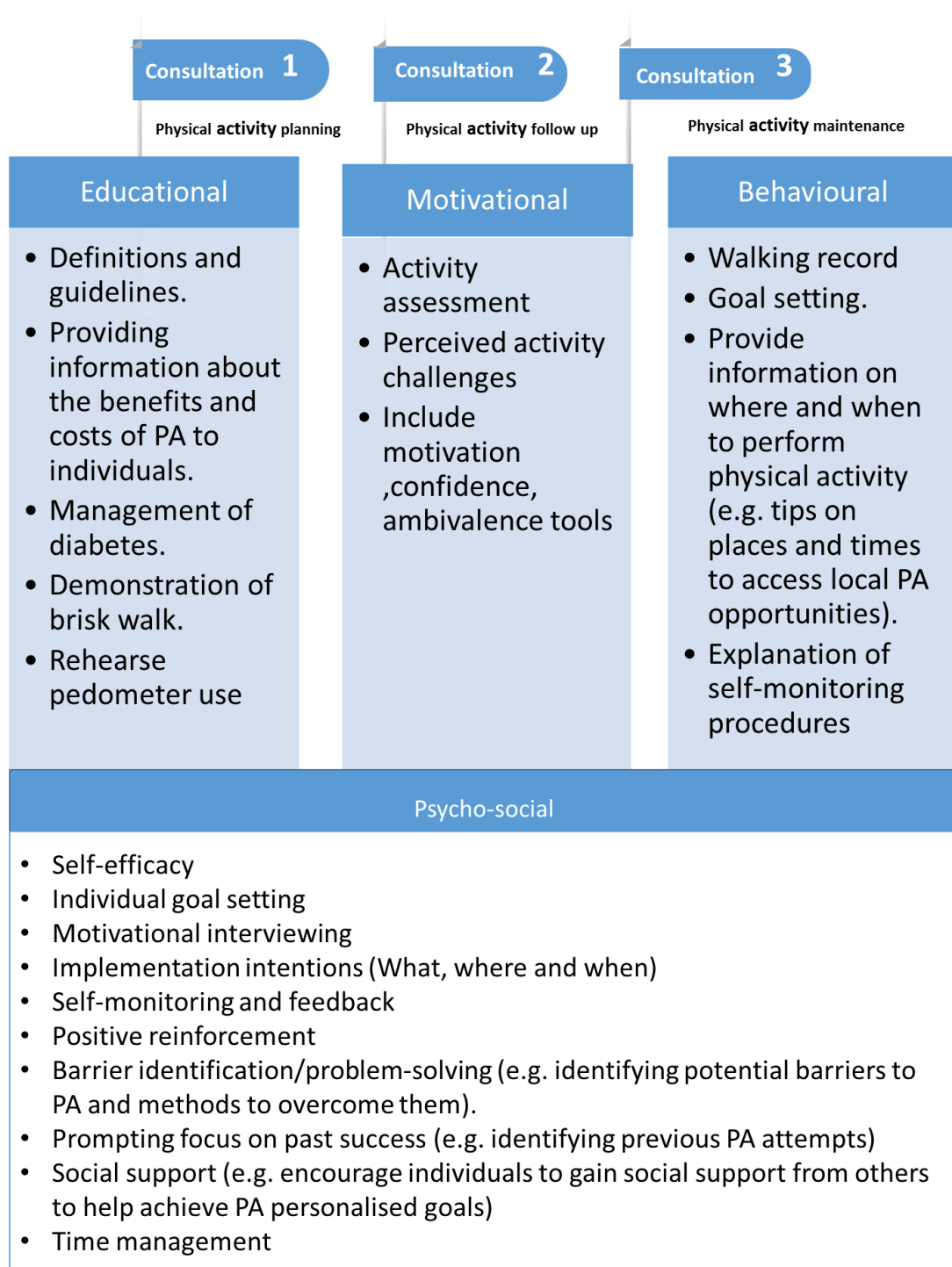
Image 7.2: The “MOVEdiabetes” Logo

The “MOVEdiabetes” personalised, multiple contact, consultations included several behavior change techniques presented earlier in Chapter 6,

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<sup>1</sup> A test for internal consistency (the degree to which multiple measures of the same thing agree with one another).

(Section 6.5.1) (Figure 7.1). The consultation workbook is presented in Appendix 7.5.



**Figure 7.1: Content of the face to face personalised physical activity consultations**

### *Pedometer*

Participant were asked to set individual goals and fill in a daily step count (see Appendix 6.8) to be submitted to the project officers in their respective health centres over a three month period, through WhatsApp on monthly basis and at 12 months. Feedback on step counts were given within the PA consultation visits and/or discussed over the WhatsApp telephone application.

### *WhatsApp phone application*

Monthly standardized PA motivational messages were delivered through this telephone application. Participants were also invited to join a WhatsApp peer support group (group setting) to share their experiences with other “MOVEdiabetes” participants or else they could chose to be in individual contact with the POs (individual setting) (see Section 6.5.3). POs initiated the WhatsApp groups, facilitated the conversations and monitored the group dynamics.

### 7.3.8 Statistical analysis

The quality of the entered data was cross-checked by staff trained in quality assurance using check lists specific to the study in a sample of 10% of questionnaires selected at random. The check lists consisted of all sections of the study questionnaire and primary and secondary outcome measures marked as fully completed, partially completed or not completed. Data were then entered into Epi Info™7 (Forbes, 2018), checked and cleaned prior to analysis. Then transferred to IBM SPSS Statistics for Windows (IBM Corp: version 22.0. Released 2012. Armonk, NY) for analysis according to the GPAQ protocol (World Health Organization, 2014b). An intention to treat analysis was performed using the last value carried forward imputation for missing data at 3 and/or 12 months and a mean imputation procedure was done where baseline



data were missing . Descriptive statistics were expressed as proportions, mean (SD), and median (IQR) at study groups level.

Due to skewness of data obtained, a univariate analysis was done in two steps. Initially, for each outcome, differences at three and 12 months from baseline were calculated and Mann–Whitney U tests used to estimate between group differences (intervention vs comparison) and the Wilcoxon Signed Rank test to estimate the within group differences. Then, a time trend for treatment effect was estimated from a Generalized Linear Model (GLM).

Furthermore, the primary outcome was dichotomised to whether or not they were meeting WHO PA recommendations (MET.min/week values  $\geq 600$ ). GLM was used to determine the between group difference in meeting the PA recommendations at three and 12 months independently.

Moreover, within the intervention group, a multivariate analysis was carried out to identify potential correlates for changes in PA at 12 months across the studied socio-demographic characteristics.

Accelerometer data of valid days, defined as 24 hours wear per day with an allowance of no more than 4 hours removal time per day over the seven days wear, with the monitor positioned in a dynamic axis orientation, were analysed using a customized activPAL3™ software (PAL Technologies Ltd, 2017). Total number of steps per day and sitting time were extracted from the accelerometers outputs, and between group differences were explored.

All participant who completed the 12 months follow up were described by socio-demographic factors. Within group differences in PA levels and cardio-metabolic factors were obtained using GLM. Additionally, differences in PA levels between individual vs group WhatsApp users were described and compared using t-test.

All five-scale responses from the 13 items in the wellbeing questions were collapsed to three categories. Then proportions of responses at baseline and 12 months from the IG and CG were compared and between study group

differences in proportions of ratings across the studied health domains were obtained using chi-squared tests. Furthermore, differences in responses between baseline and 12 months were then calculated and categorised into: “improved” (if score was in a favourable direction), “no change” (if score was 0), or “worsen” (if score was in an un-favourable direction). Between groups differences in the proportions of the categorised responses were then obtained using chi-squared test.

Additionally, spearman correlation analysis was utilised to find associations between changes (as ordinal variables) in general health, sleep, mental health, pain and quality of life with the change in self-reported PA levels (MET.min/week).

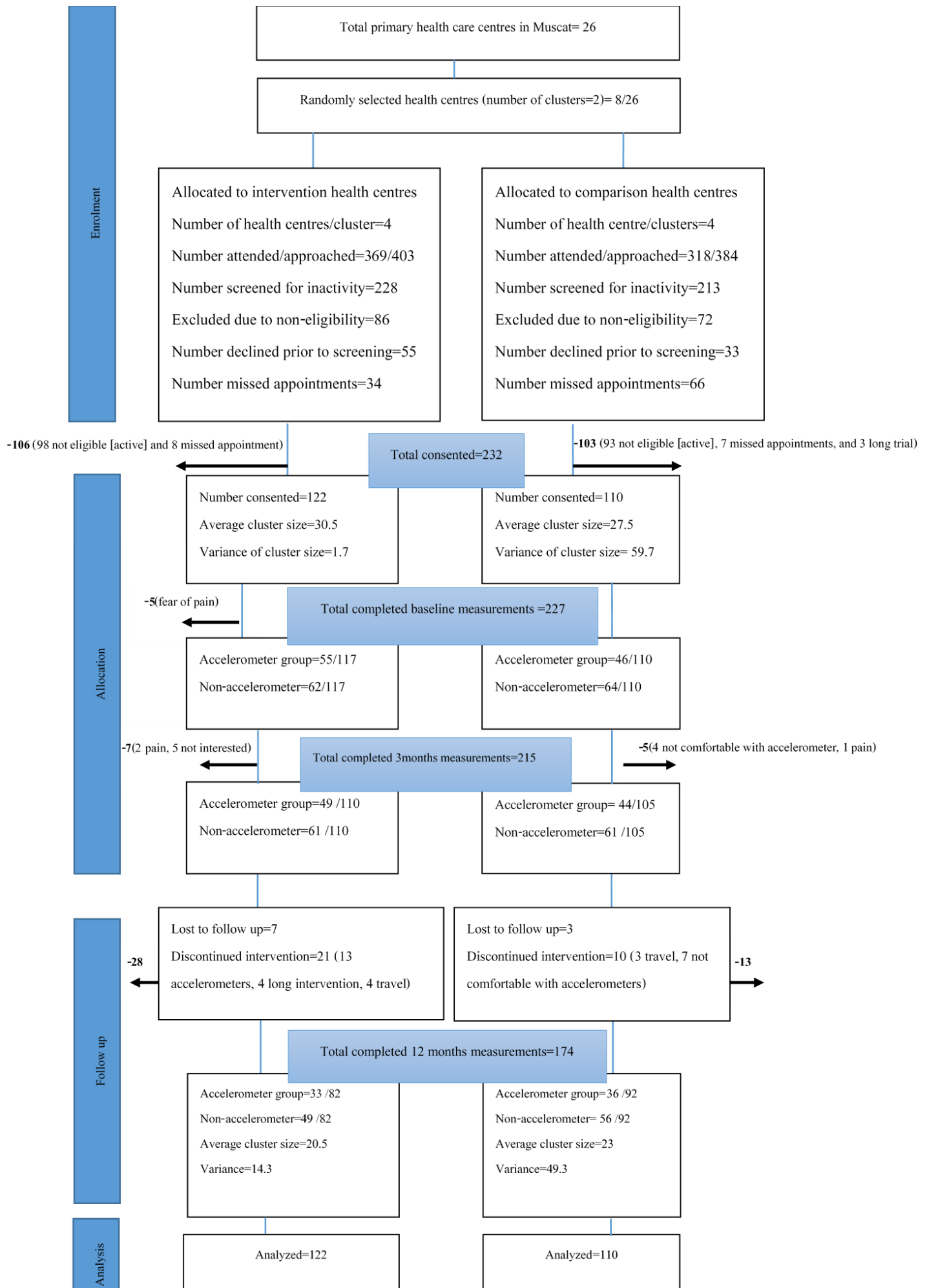
## 7.4 Results

### 7.4.1 *Recruitment, retention and attrition*

Of the 441 participants who were screened for inactivity, 98 in the IG vs 93 in the CG were physically active and hence excluded from the study. Of the remaining 130 participants in the IG and 120 in the CG (total of 250 eligible inactive participants), eight vs seven missed their appointments for giving consent in the IG vs CG respectively. Three participants from the CG dropped out from the study and the remaining 232/250 eligible participants (92.8%) consented to participate in the study. In total 174/232 (75%) completed the 12 months follow up study measurements at baseline, 3 and 12 months follow up (117 IG vs 110 CG, 110 IG vs 105 CG and 82 IG vs 92 CG, respectively). Figure 7.2 presents the CONSORT flowchart that describes the progress of participants throughout the 12 months follow up study.

Overall, out of 232 participants who, 227 (provided consent 97.8%) completed baseline measurements, 215 (92.7%) completed 3 months follow-up measurements and 174 (75%) completed the final 12 month measurements.

The reasons for attrition (IG n=40, CG n=18) are presented in the CONSORT diagram (Figure 7.2) and the most frequently reported reasons were feeling uncomfortable with the accelerometers (41%), joint pain (14%), travel outside of Oman (12%), or being lost to follow up without a reason being given (17%).



**Figure 7.2: CONSORT flowchart describing progress of participants through the 12 months follow up study**

#### 7.4.2 Participants' socio-demographic and physiological characteristics

At baseline, more than half of participants in both the intervention and comparison groups were females (64.5% and 54.1%, respectively), and the mean age (SD) of the total population was 44.2 (8.1) with a range of 22-68 years. The majority of the population (79.3%) were married and half (50.9%) had completed their secondary education. Income was reported by 87.5% of the total population, of which more than half reported a moderate income of ≤1000 Omani rials/month. Additionally, more than half of the total population were employed, with a higher percentage in the intervention than comparison group (65.6% vs 50% respectively). The two groups were similar in social status except for marital status (more married individuals in the CG vs IG) ( $P=0.03$ ) and employment status (more employed individuals in the IG vs CG) ( $P=0.02$ ) (Table 7.1).

Mean (SD) duration of diabetes for the total population was 5.8(3.7) years and 77.2% of them reported comorbidities mainly hypertension (45.3%) or hyperlipidaemia (35.6%) or both (15%) for which all were on anti-hypertensives or statins (lipid reducing drugs) or both accordingly. Most (81%) of the sample (84.5% IG vs 77.3% CG) were on oral hypoglycaemic drugs, of which 13.8% also used insulin (9.8% IG vs 18.2% CG,  $P=0.07$ ) (Table 7.1).

**Table 7.1: Participants' socio-demographic characteristics, presence of comorbidities, diabetes duration and treatment in the treatment group**

Characteristics	Intervention group	Comparison group	Total population
	n=122 (52.6%)	n=110 (47.4)	n=232 (%)
Gender			

Male	56(45.9)	39(35.5)	95(40.9)
Female	66(54.1)	71(64.5)	137(59.1)
Age (years)			
Mean (SD)	43.5(7.1)	45.1(9.2)	44.2(8.1)
≤44	65(53.3)	48(43.6)	113(48.7)
>44	57(46.7)	62(56.4)	119(51.3)
Marital status			
Currently Unmarried	32(26.2)	16(14.5)	48(20.7)
Currently married	90(73.8)	94(85.5)	184(79.3)
Education			
≤ secondary	62(50.8)	52(47.3)	114(49.1)
> secondary	60(49.2)	58(52.7)	118(50.9)
Income (Omani Rials)*			
≤1000 per month	70(57.4)	55(50)	125(53.9)
>1000 per month	41(33.6)	37(33.6)	78(33.6)
Employment			
Currently unemployed	42(34.4)	55 (50)	97(41.8)
Currently employed	80(65.6)	55(50)	135(58.2)
Mean duration of diabetes (SD)			
≤5yrs	63(51.6)	52(47.3)	115(49.6)
>5yrs	59(48.4)	58(52.7)	117(50.4)

Comorbidities**			
No comorbidities	27(22.1)	26(23.6)	53(22.8)
With comorbidities	95(77.9)	84(76.4)	179(77.2)
Diabetes medication			
Diet only	7(5.7)	5(4.5)	12(5.2)
Oral hypoglycaemic drugs	103(84.5)	85(77.3)	188(81.0)
Oral hypoglycaemic + Insulin	12(9.8)	20(18.2)	32(13.8)

\* 29 missing values due to reporting "I don't know"

\*\* Presence of hypertension, hyperlipidaemia, thyroid, or any other condition coinciding with diabetes registered in the health information system

At baseline, mean (SD) BMI was  $>30 \text{ kg/m}^2$  in both groups. Mean systolic blood pressure (SBP) levels were within target levels of  $<140 \text{ mmHg}$  in both the groups. Mean (SD) diastolic blood pressure was significantly higher in the IG [83.2(9.4) mmHg] than the CG [78.7(14.4) mmHg] ( $P=0.003$ ). Mean (SD) HbA1c in both groups was  $>7.0\%$  [8.1 (1.7)% IG vs 7.8 (1.7)% CG] indicating poor diabetes control according to the Omani diabetes management guidelines (Ministry of Health Oman, 2015). Average levels of total cholesterol, and LDL, in both groups, were higher than the target limits. However, HDL and TG levels were all within target limits<sup>1</sup>. There were no significant between group differences in BMI, SBP, HbA1c, and lipid profile at baseline (Table 7.2).

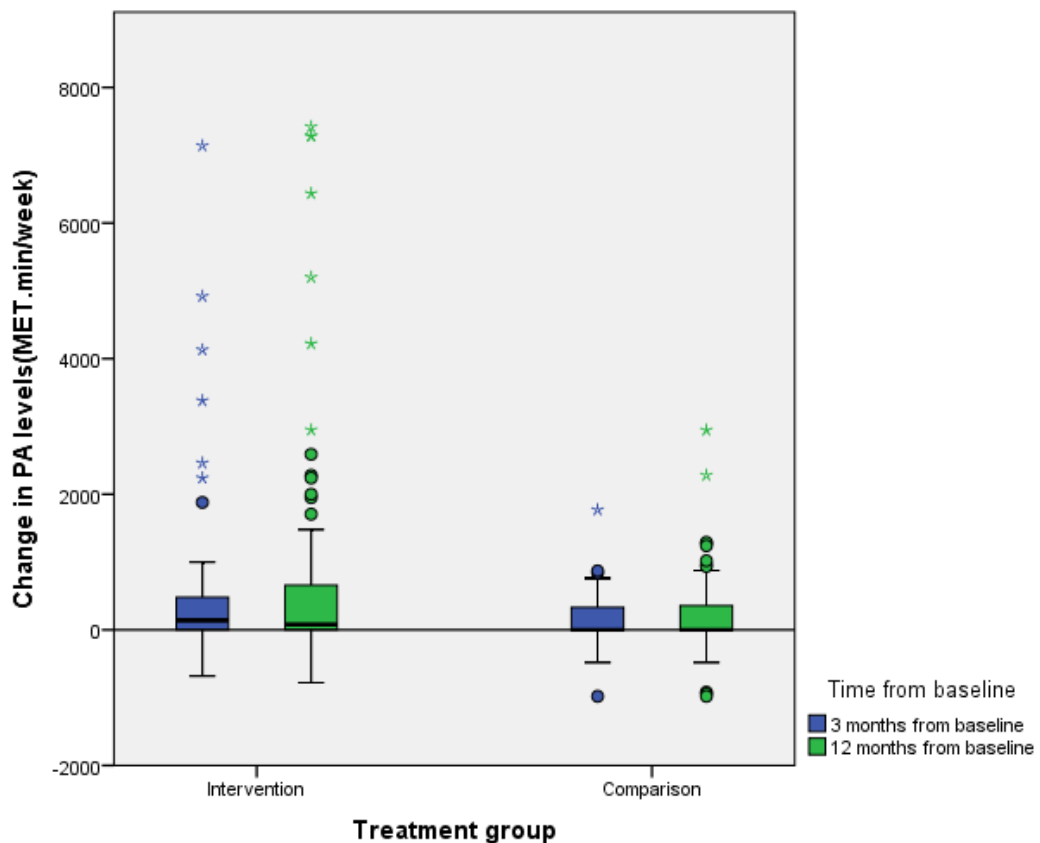
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<sup>1</sup> All target values are based on the Oman diabetes mellitus management guidelines (2015): BMI  $18.5\text{--}25 \text{ kg/m}^2$ , HbA1c  $\leq 7\%$ , SBP/DBP  $<140/<80 \text{ mmHg}$ , cholesterol  $<5.0 \text{ mmol/L}$ , HDL  $>1.0 \text{ mmol/L}$ , LDL  $<2.6 \text{ mmol/L}$ , TG  $<1.7 \text{ mmol/L}$ .

### 7.4.3 Change in primary outcome (PA levels)

Overall, about two thirds (68.9%) of the calculated PA level (MET.min/week) was attributed to leisure activity followed by 28.6% by travel and 2.5% by work. The dominance of leisure activity as the main contributor to the overall PA levels was prominent in both groups at all measurement points and more importantly, to the overall changes in PA levels.

At baseline there was no difference in median PA levels between the groups ( $P=0.08$ ). However, at 3 and 12 month follow-up the median (IQR) change in PA from baseline was significantly greater in the IG than CG at both time-points: +17% at 3 months (+140 (0, 480) vs 0 (0, 330) MET.min/week, respectively,  $P=0.04$ ) and +26% at 12 months (+80 (0, 663) vs 0 (-7.5, 361) MET.min/week, respectively,  $P=0.01$ ) (Figure 7.3).



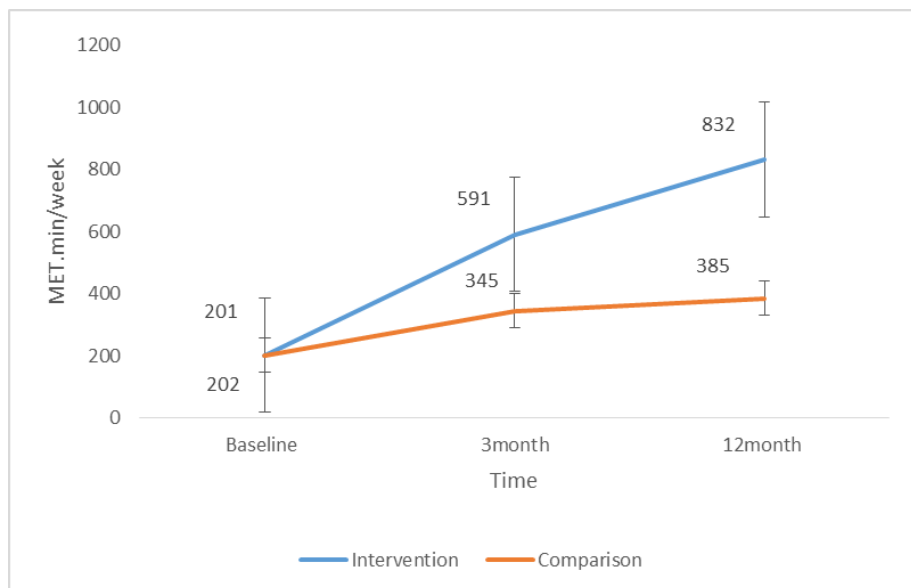
Between group differences  $P=0.04$  at 3 months, and  $P=0.01$  at 12 months



**Figure 7.3: Change in physical activity levels from baseline at 3 and 12 months by treatment group**

Figure 7.4 illustrates the steady increase in PA levels in both treatment groups, but in particular, the significantly higher mean gain from baseline in the IG than the CG at 12 months [ $+447.4$  (95%CI 150.7 to 744.1) MET.min/week,  $P=0.003$ ]. Additionally, at 12 months, mean change in MET.min/week was  $+631.3$  (95%CI 369.4 to 893.2) in the intervention group (IG) vs  $+183.2$  (95%CI 83.3 to 283.0) in the comparison group (CG).

Multivariate analysis within the IG for the best statistical model to explain the gain in PA levels at 12 months across the studied socio-demographic factors showed a significantly greater increase of  $+500$  MET.min/week ( $P=0.04$ , 95%CI 33.0 to 1144.4) in individuals with high vs low education and  $+600$  MET.min/week ( $P=0.02$ , 95%CI 127.7 to 1278.6) in individuals with high vs low income.



**Figure 7.4: Mean (SE) change in mean physical activity levels (MET.min/week) in the treatment groups over 12 months**

Additionally, despite no significant differences at baseline, odds of meeting PA WHO recommendations were significantly higher, by 1.8 ( $P=0.04$ , 95%CI 1.1 to 3.1) and 1.9 ( $P=0.02$ , 95%CI 1.2 to 3.3) times, in the IG compared to CG at 3 and 12 months, respectively (Table 7.3). Notably, meeting the recommendations at 12 months was strongly positively correlated with changes in MET.min/week in both the study groups ( $r=0.75$  in the IG vs  $r=0.74$  in the CG,  $P=0.001$ ). However, meeting the recommendations was, although weak, significantly (negatively) correlated with changes in HbA1c, and sitting time in the total population ( $r=-0.19$  and  $-0.18$ ,  $P=0.004$ , and  $0.007$  respectively), and BMI, HbA1c, TG and sitting time in the IG ( $r= -0.20$ ,  $-0.30$ ,  $-0.24$ , and  $-0.29$ ,  $P=0.03$ ,  $0.001$ ,  $0.009$ , and  $0.001$  respectively). However, except for the weak negative correlation between meeting the recommendation and DBP ( $r=-0.19$ ,  $P=0.04$ ) no other significant associations were found.

At 12 months, meeting the recommendations was significantly associated with younger vs older age in the IG (OR= 1.1,  $P=0.005$ ) and younger vs older age and high vs low income in the CG (1.5,  $P=0.006$  and OR=1.4,  $P=0.014$  respectively).

**Table 7.2: Changes in primary [physical activity (MET.min/week) and sitting time (hours/day)] and secondary outcome measures from baseline to 3 and 12months, by treatment group**

Measures	Baseline		3months			12months			Between group difference, P value	
	No	Mean (SD)	No	Mean (SD)	Difference to baseline	No	Mean (SD)	Difference to baseline	3months	12months
Primary outcome:										
Self-reported PA Average MET.min/week										
Intervention	117	200.9(341.5)	110	591.1(1054.2)	+390.2(977.6)	82	832.2(1514.7)	+631.3(1461.1)	+245.9	+447.4
Comparison	110	201.6(235.1)	105	345.2(368.4)	+143.5(329.4)	92	384.8(523.9)	+183.2(528.5)	(39.2 to 452.6)	(150.7 to 744.1)
									0.02*	0.003*
Secondary outcomes:										
Objectively measured steps/day										



[illegible]

Diastolic blood pressure (mmHg**)										
Intervention	117	83.2(9.4)	110	82.0(6.6)	-1.1(9.3)	82	80.0(4.2)	-3.1(9.4)	+0.9	-1.6
Comparison	110	78.7(14.4)	105	81.1(8.5)	+0.5(13.1)	92	81.7(5.4)	+3.0(0.7)	(-1.0 to 2.9) 0.36	(-2.6 to -0.7) 0.001*
Fasting cholesterol (mmol/L)**										
Intervention	117	5.0(1.2)	110	4.8(0.7)	-0.2(0.9)	82	4.5(1.0)	-0.5(1.1)	-0.005	-0.08
Comparison	110	4.9(1.0)	105	4.9(0.9)	-0.1(0.7)	92	4.6(0.8)	-0.3(0.9)	(-0.2 to 0.2) 0.96	(-0.3 to 0.2) 0.51
HDL(mmol/L)**										
Intervention	117	1.6(1.2)	110	1.6(0.7)	-0.15(1.2)	82	1.9(0.9)	-0.04(1.5)	+0.03	+0.1
Comparison	110	1.8(1.5)	105	1.6(1.1)	-0.01(1.3)	92	1.8(0.8)	+0.3(1.6)	(-0.3 to 0.2) 0.77	(-0.1 to 0.3) 0.31

LDL(mmol/L)**										
Intervention	117	2.9(1.0)	110	2.9(0.9)	-0.1(0.5)	82	2.4(0.9)	-0.3(0.9)	-0.04	-0.2
Comparison	110	3.0(0.9)	105	2.9(0.9)	-0.1(0.9)	92	2.6(0.9)	-0.7(1.2)	(-0.3 to 0.2)	(-0.5 to 0.1)
									0.75	0.14
TG(mmol/L)**										
Intervention	117	1.4(0.6)	110	1.4(0.8)	+0.1(0.7)	82	1.3(0.5)	-0.09(0.3)	-0.1	-0.3
Comparison	110	1.5(0.9)	105	1.6(1.0)	+0.04(0.8)	92	1.6(1.0)	+0.05(0.7)	(-0.4 to 0.1)	(-0.5 to -0.08)
									0.25	0.006*

\*P<0.05, Body mass index (BMI), Glycated haemoglobin (HbA1c), High-density lipoprotein (HDL), Low-density lipoprotein (LDL), Triglycerides (TG)

\*\*\* Significant within group difference at 12 months from baseline using non-parametric test (Wilcoxon Signed Rank Test)

**Table 7.3: Odds of meeting the PA recommendation at baseline, 3 and 12months**

N(%)	Baseline (%)			3 months (%)			12months (%)		
		OR	95%CI,		OR	95%CI,		OR	95%CI,
			P value			P value			P value
Intervention	13(10.7)	1.7	0.6 to 4.6	46(37.7)	1.8	1.1 to 3.1	52(42.6)	1.9	1.2 to 3.3
N=122(52.6)			0.3			0.04			0.02
Comparison	7(6.4 )	ref		28(25.5)	ref		31(28.2)	ref	
N=110(47.4)									

#### 7.4.4 Secondary outcomes

##### Objectively measured step counts/day

Around half (48%) (n=59) of participants in the IG vs 40% (n=44) in the CG used accelerometers at baseline. Overall, 69 participants (67%) had completed accelerometer use at both baseline and 12 months (33 in the IG vs 36 from the CG). The average (SD) number of valid days (minimum of four valid days with no more than 2 hours removal per day and the device is in the dynamic axis) at baseline, 3 and 12 months was 5.7(1.0) [n=45], 5.3(1.2) [n=38] and 5.3(1.3) [n=28] in the IG and 5.9(1.0) [n=39], 5.4(0.93) [n=32] and 5.9(1.1) [n=30] in the CG, respectively.

Between study group average number of steps/day at baseline were comparable (P=0.1). The average number of steps/day initially increased in the IG only at 3 months, thereafter increasing in both groups, such that the overall increase from baseline at 12 months was significantly greater in the IG than the CG (Table 7.2). Overall at 12 months average change in steps /day was +757 steps/day higher in the intervention compared to the comparison group (P= 0.05, 95%CI -18 to 1531).



### Sitting time

Sitting time (hours/day) was found to change from 13.1(2.4) to 12.2(1.9) at 3 months to 12.2(2.2) at 12 months within the IG vs a change from 13.7(1.0) at baseline to 13.6(1.2) at 3 months to 13.7(1.4) at 12 months within the CG. Moreover, there was a significantly greater reduction in sitting time (hours/day) in the IG vs CG at both 3 and 12 months, by -1.3 (95%CI -2.2 to -0.6) and -1.5(95%CI -2.4 to -0.7) hours per day, respectively (Table 7.2).

### Weight, BMI, HbA1c, BP, lipid profile

Table 7.2 illustrates the lack of any between group differences in changes in weight, BMI or HbA1c. However, there were significantly greater reductions in the IG compared to CG in: SBP by -3.8 (95%CI -6.7 to -0.9) mmHg, ( $P=0.008$ ) at 3 months and -1.8 (95%CI -2.6 to -0.7) mmHg, ( $P=0.04$ ) at 12 months, and in DBP by -1.6 (95%CI -2.6 to -0.7) mmHg, ( $P=0.001$ ), at 12 months. Additionally, a significantly greater reduction in triglycerides (TG) levels of -0.3 95%CI -0.5 to -0.08) mmol/L, ( $P=0.006$ ), was observed in the IG vs CG at 12 months.

Nonetheless, despite no between group differences in change in weight, BMI and HbA1c, significant within group difference for median weight ( $P<0.001$ ), BMI ( $P<0.001$ ) and HbA1c ( $P=0.03$ ) were found in the IG between baseline and 12 months indicating a possible study effect or secular changes.

### Results from the wellbeing questionnaire

#### Ratings at population level (baseline and 12 months)

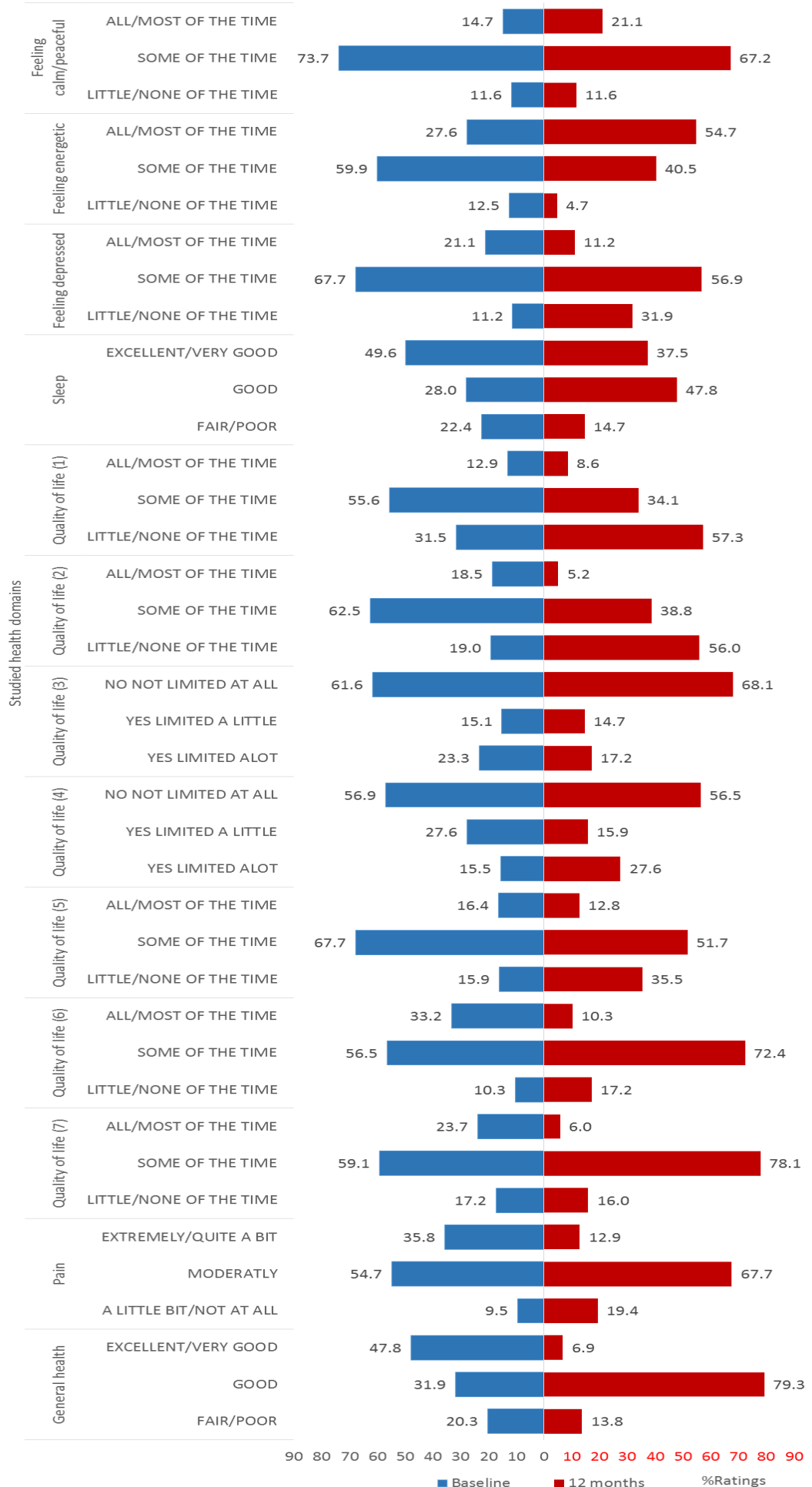
Looking overall at the results of the questions on wider health domains at 12 months and baseline provides insight to some general health issues in this study population. The whole sample ( $n=232$ ) showed a range of responses across the studied health domains (**Error! Reference source not found.**). Notably, at 12 months from baseline the greatest proportions of ratings were positive, and this was the case in most health domains.

Reporting 'all/most of the times' to feeling calm/peaceful and energetic increased at 12 months from baseline. Overall, there were significant differences in proportions for the ratings for feeling calm/peaceful ( $P<0.001$ ) and energetic ( $P=0.02$ ), but not for feeling downhearted/depressed at 12 months from baseline ( $P=0.9$ ).

Ratings for sleep seemed to improve at 12 months from baseline (reporting fair/poor reduced from 22.4% to 14.7%). Overall, ratings for sleep were significantly different at 12 months from baseline ( $P=0.01$ ).

In general, ratings across all the items related to QOL showed improvements at 12 months from baseline. However, significant differences in the proportion of ratings at 12 months from baseline were only noted within accomplishing less because of physical health [QOL1 ( $P=<0.001$ )], limitations as a result of physical health [QOL2 ( $P=<0.001$ )], and limitations on amounts of vigorous activities [QOL3 ( $P=0.03$ )].

Despite improvements at 12 months, differences in proportion of ratings were not significant neither for pain nor for general health ( $P=0.4$  and  $0.1$  respectively) (**Error! Reference source not found.**).



(1) Accomplished less because of physical health, (2) Limitations as a result of physical health, (3) Limitations in the amounts of vigorous activities, (4) Limitations in the amounts of moderate activities, (5) Accomplished less because of emotional problems, (6) Limitations as a result of emotional problems, (7) Physical health and emotional problems interfering with social activities.

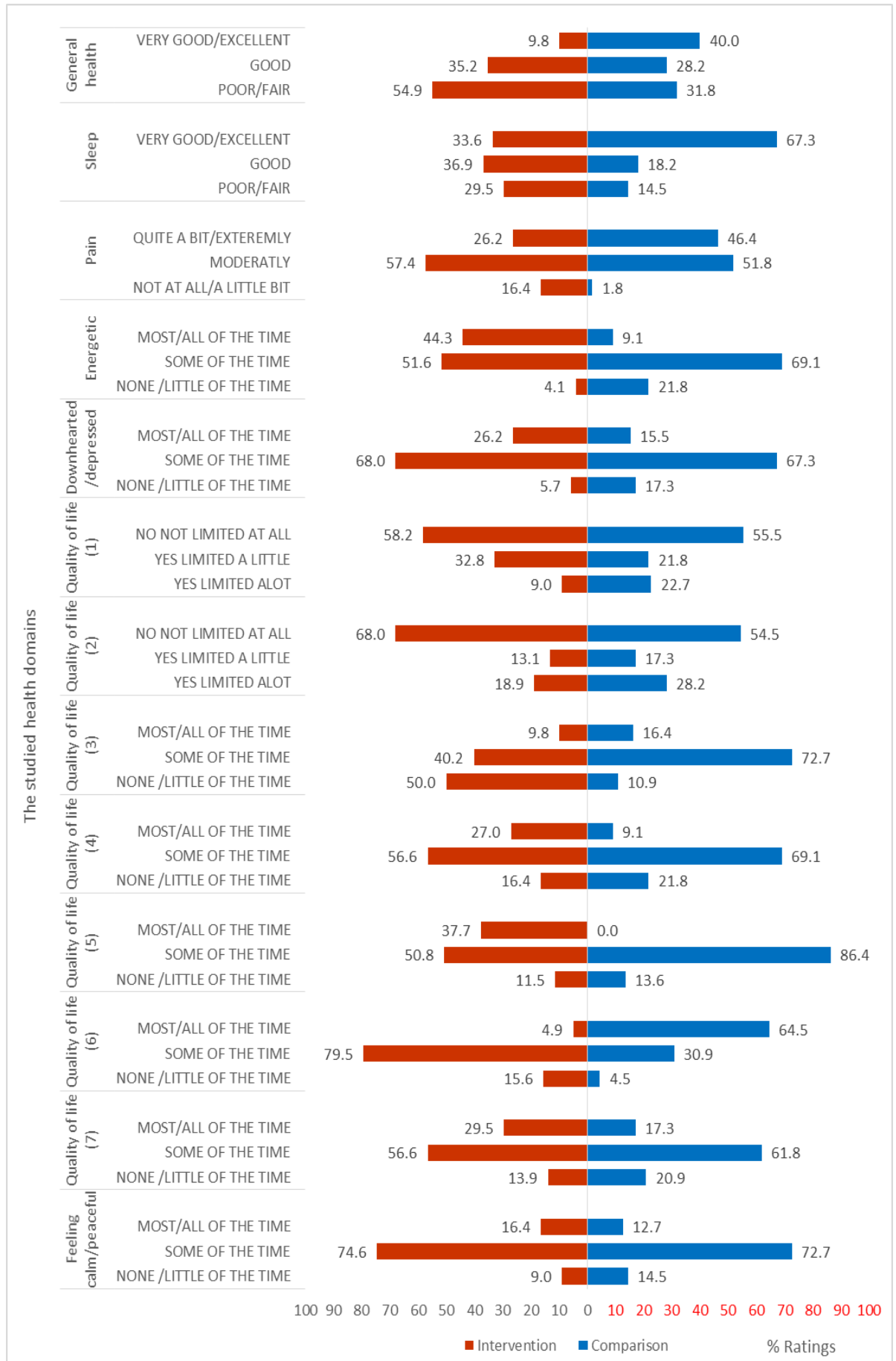
Figure 7.5: Ratings on items in the general wellbeing questionnaire across the studied health domains at population level (baseline and 12 months)

Between group differences in ratings to the general wellbeing questionnaire at baseline

Between group differences in the proportion of ratings were significantly better (in favour of intervention group) except for: a) ratings on feeling calm/peaceful, [majority of the participant in both the study groups felt calm and peaceful 'some of the time' ( $P=0.4$ ), b) social restrictions as a result of physical and emotional health ( $P=0.6$ ) and c) limitation in vigorous activities ( $P=0.6$ ) (**Error! Reference source not found.**).

At baseline, more than half of the participant in the IG (54.9%) rated their general health as poor/fair vs 31.8% in the CG indicating poor perceptions on general health in the IG ( $P<0.001$ ). Only 33.6% in the IG vs the majority of the participants in the CG perceived their sleeping as very good to excellent ( $P<0.001$ ). However, more than half of the participants in both the study groups perceived pain as moderate ( $P<0.001$ ), felt energetic some of the time ( $P<0.001$ ) and felt down hearted/depressed some of the time ( $P=0.007$ ).

Ratings for questions on QOL varied between the study groups. Notably (with the exception for ratings on limitations as a result of emotional problems), a greater proportion of participant in both the study groups perceived limitations to all the other questions on QOL 'some of the time' (**Error! Reference source not found.**).



(1) Limitations in the amounts of moderate activities, (2) Limitations in the amounts of vigorous activities, (3) Accomplished less because of physical health, (4) Limitations as a result of physical health, (5) Accomplished less because of emotional problems, (6) Limitations as a result of emotional problems, (7) Physical health and emotional problems interfering with social activities.

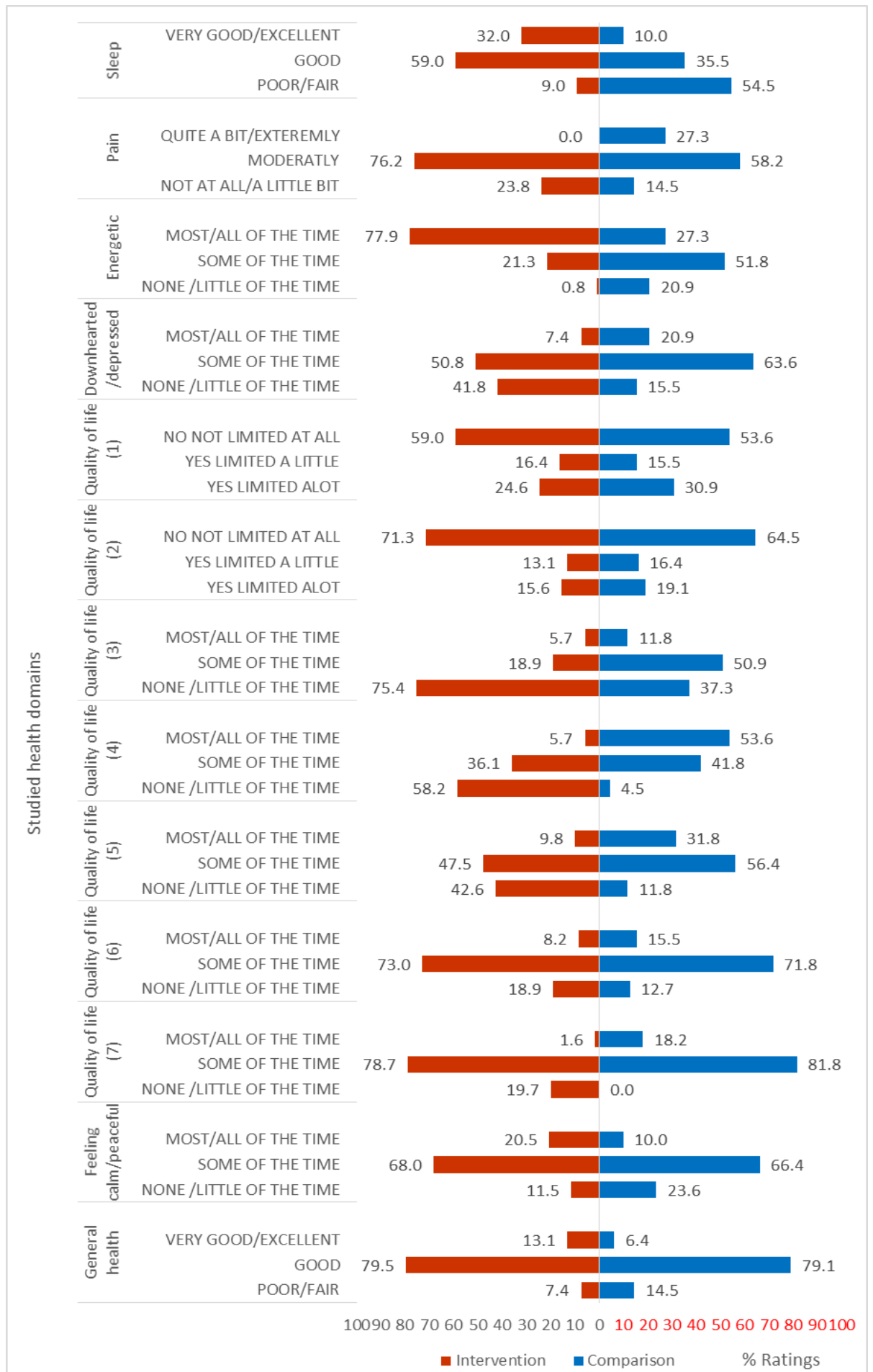
Figure 7.6: Between the study groups' ratings on items in the general wellbeing questionnaire across the studied health domains at baseline

Between study group differences in ratings to the general wellbeing questionnaire at 12 months

At 12 months, between study groups differences in proportions of ratings for sleep, and feeling pain, energetic, or downhearted/depressed were significant ( $P = 0.001$ ,  $P < 0.001$ ,  $P < 0.001$ ,  $P < 0.001$ , respectively). Greater proportions of participant in the IG vs CG reported 'very good/excellent' sleep, 'not at all/a little bit' of pain, and feeling energetic 'most/all of the time' and downhearted/depressed 'none/little of the time' (32.0% vs 10.0%, 23.8% vs 14.5%, 77.9% vs 27.3% and 41.8% vs 15.5% respectively).

Between groups' ratings for QOL were not significantly different [with the exception of ratings on accomplishing less because of physical health [QOL3 ( $P < 0.001$ )] (Figure 7.7).

Most participants in both the study groups rated 'some of the time' to feeling calm/peaceful and 'good' for general health. Between group differences in these ratings were not significant ( $P = 0.3$  and  $0.8$ , respectively).



(1) Limitations in the amounts of moderate activities, (2) Limitations in the amounts of vigorous activities, (3) Accomplished less because of physical health, (4) Limitations as a result of physical health, (5) Accomplished less because of emotional problems, (6) Limitations as a result of emotional problems, (7) Physical health and emotional problems interfering with social activities.

Figure 7.7: Between the study groups' ratings on items in the general wellbeing questionnaire across the studied health domains at 12 months

Between group differences in change in responses at 12 months from baseline

Differences in responses at 12 months from baseline was categorised as indicated in **Error! Reference source not found.**. The proportion of participants who improved was greater in the IG vs CG in all the items in the questionnaire except for questions 3 (limitations in the kinds or amounts of moderate activity) and 5 (feeling calm and peaceful), where improvement were greater in the CG vs IG. Notably, the proportion of participants who worsened was lower in the IG vs CG for all questions except question 5 (accomplishing less due to physical health) where both the study groups had a similar proportion of participant who worsened (16.4%) and question 6 where a higher proportion worsened in the IG than the CG (18.9% vs 10%).

The differences in the proportion of individuals who improved vs didn't change vs worsened was significant for questions one [general health ( $P=0.006$ )] and six to eleven [limitations due to physical problems ( $P=0.02$ ), accomplished less due to emotional problems ( $P=0.03$ ), limitations due to emotional problems ( $P<0.001$ ), limitations due to pain ( $P=0.02$ ), feeling peaceful and calm ( $P=0.04$ ), and energetic ( $P<0.001$ )]. All improvements were in favour of the IG (**Error! Reference source not found.**). Differences in proportions were borderline ( $P=0.05$ ) for perceptions on sleep (Q2) and social restrictions (Q13).

Positive, significant associations were shown between changes in self-reported PA (MET.min/week) (see Section 7.3.3) and the health domains in the



questionnaire for both the IG & CG on responses for general health ( $r=0.70$  &  $0.36$ ,  $P<0.001$ ), feeling calm/peaceful ( $r=0.86$  &  $0.93$ ,  $P<0.001$ ) and feeling energetic ( $r=0.86$  &  $0.82$ ,  $P<0.001$ ). Additionally, a strong negative association was revealed between change in PA levels and changes in feeling depressed ( $r=-0.35$ ,  $P<0.001$  &  $-0.30$ ,  $P=0.001$ ). Other significant associations between change in PA levels within the IG, were noted with restrictions due to emotional health ( $r=0.26$ ,  $P=0.004$ ) and pain ( $r=-0.29$ ,  $P=0.001$ ). However, sleep was significantly associated with PA levels within the CG ( $r=0.35$ ,  $P=0.005$ ).

**Table 7.4: Between group differences in proportion of responses to questions on general health, sleep, mental health and quality of health (improved, no change or worsened) and correlation with change in PA levels (MET.min/week)**

Questions	Total population n=232(%)	Intervention n=122(%)	Comparison n=110(%)	Corrected $\chi^2$ P-value
Q1 In general, would you say your health is?				7.88
Improved	95(40.9)	59(48.4)	36(32.7)	0.02
No change	50(21.6)	27(22.1)	23(20.9)	
Worsened	87(37.5)	36(29.5)	51(46.4)	
Correlation with change in MET.min/week	0.55**	0.70**	0.36**	
Q2 In general, would you say your sleep is?				
Improved	101(43.5)	55(45.1)	46(41.8)	5.84
No change	65(28.0)	40(32.8)	25(22.7)	0.05
Worsened	66(28.4)	27(22.1)	39(35.5)	

Correlation with change in MET.min/week	0.28**	0.18	0.35**	
Q3 Does your health now limit you in the kinds or amounts of moderate activities you can do, like moving a table, carrying groceries, or bowling?				1.57
Improved	82(35.3)	43(35.2)	39(35.5)	0.46
No change	82(35.3)	47(38.5)	35(31.8)	
Worsened	68(29.3)	32(26.2)	36(32.7)	
Correlation with change in MET.min/week	-0.05	-0.11	0.008	
Q4 Does your health now limit you in the kinds or amounts of vigorous activities you can do, like lifting heavy objects, running or participating in strenuous sports?				3.56
Improved	49(21.1)	26(21.3)	23(20.9)	0.17
No change	118(50.9)	68(55.7)	50(45.5)	
Worsened	65(28)	28(23)	37(33.6)	
Correlation with change in MET.min/week	-0.04	-0.11	0.06	
Q5 How much of the time have you accomplished less in certain kinds or amounts of work, or housework, because of your PHYSICAL HEALTH?				0.24
Improved	104(44.8)	53(43.4)	51(46.4)	0.89
No change	90(38.8)	49(40.2)	41(37.3)	
Worsened	38(16.4)	20(16.4)	18(16.4)	
Correlation with change in MET.min/week	-0.11	-0.09	-0.12	
Q6 How much of the time you had limitations in the kind of work or other activities as a result of your PHYSICAL HEALTH?				7.80
Improved	141(60.8)	77(63.1)	64(58.2)	0.02
No change	57(24.6)	22(18.0)	35(31.8)	

Worsened	34(14.7)	23(18.9)	11(10.0)	
Correlation with change in MET.min/week	-0.15	-0.11	-0.17	
Q7 How much of the time have you Accomplished less in certain kinds or amounts of work, or housework, because of your EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?				7.03
				0.03
Improved	91(39.2)	31(25.4)	13(11.8)	
No change	97(41.8)	46(37.7)	51(46.4)	
Worsened	44(19)	45(36.9)	46(41.8)	
Correlation with change in MET.min/week	0.13*	0.26**	0.03	
Q8 How much of the time you had limitations in the kind of work or other activities as a result of any EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?				33.53
				<0.001
Improved	28(12.1)	23(18.9)	5(4.5)	
No change	116(50.0)	73(59.8)	43(39.1)	
Worsened	88(37.9)	26(21.3)	62(56.4)	
Correlation with change in MET.min/week	0.04*	0.16	0.01	
Q9 How much bodily pain have you had during the past 4 weeks?				7.44
Improved	105(45.3)	56(45.9)	49(44.5)	0.02
No change	55(23.7)	45(36.9)	34(30.9)	
Worsened	72(31.0)	21(17.2)	27(24.5)	
Correlation with change in MET.min/week	-0.17**	-0.29**	-0.06	
Q10 Have you felt calm and peaceful during the last 4 weeks?				6.34
Improved	122(52.6)	71(58.2)	51(46.4)	0.04

No change	68(29.3)	36(29.5)	32(29.1)	
Worsened	42(18.1)	15(12.3)	27(24.5)	
Correlation with change in MET.min/week	0.90**	0.86**	0.93**	
Q11 Did you have a lot of energy during the past 4 weeks?				16.07
Improved	122(52.6)	79(64.8)	44(40)	<0.001
No change	68(29.3)	31(25.4)	39(35.5)	
Worsened	42(18.1)	12(9.8)	27(24.5)	
Correlation with change in MET.min/week	0.84**	0.86**	0.82**	
Q12 Have you felt downhearted and depressed during the past 4 weeks?				1.73
Improved	136(58.6)	75(61.5)	61(55.5)	0.42
No change	33(14.2)	14(11.5)	19(17.3)	
Worsened	63(27.2)	33(27)	30(27.3)	
Correlation with change in MET.min/week	-0.33*	-0.35**	-0.30*	
Q13 How much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting friends, relatives)?				5.87
Improved	79(34.1)	50(41)	29(26.4)	0.05
No change	120(51.7)	58(47.5)	62(56.4)	
Worsened	33(14.2)	14(11.5)	19(17.3)	
Correlation with change in MET.min/week	-0.03	-0.05	0.18	

\* Significant results  $P < 0.05$ , \*\* significant results  $P < 0.05$

Notably, the Cronbach's alpha test revealed poor internal consistency of this tool in this study population (values =0.50).

#### 7.4.5 *Analysis by health centre (intervention group)*

##### *Socio-demographic characteristics*

The socio-economic characteristics of participants in the intervention group across the health centres are shown in (**Error! Reference source not found.**). In all the four health centres, more than half of participants were females, mean age (SD) was divided around 44 (7.0) and the majority were married. However, participants in HC1 vs other HC, were with higher education, income and employment. More than half of the participant in HC1 had diabetes duration of  $\leq 5$  (2.6) years and with no comorbidities compared to other health centres.

Mean levels of baseline BMI were high ( $>30$  kg/m<sup>2</sup>) among all study health centres indicating obesity. Systolic blood pressure was at normal levels, diastolic blood pressure was higher than recommended levels, and HbA1c was high in all health centres indicating uncontrolled diabetes. Except for a few sporadic readings, values from the lipid profile were all within normal limits. The normality of blood pressure, lipid profile in this population probably reflects the use the anti-hypertensive and/ lipid lowering drugs.

**Table 7.5: Socio-demographic characteristics of participants in the intervention health centres**

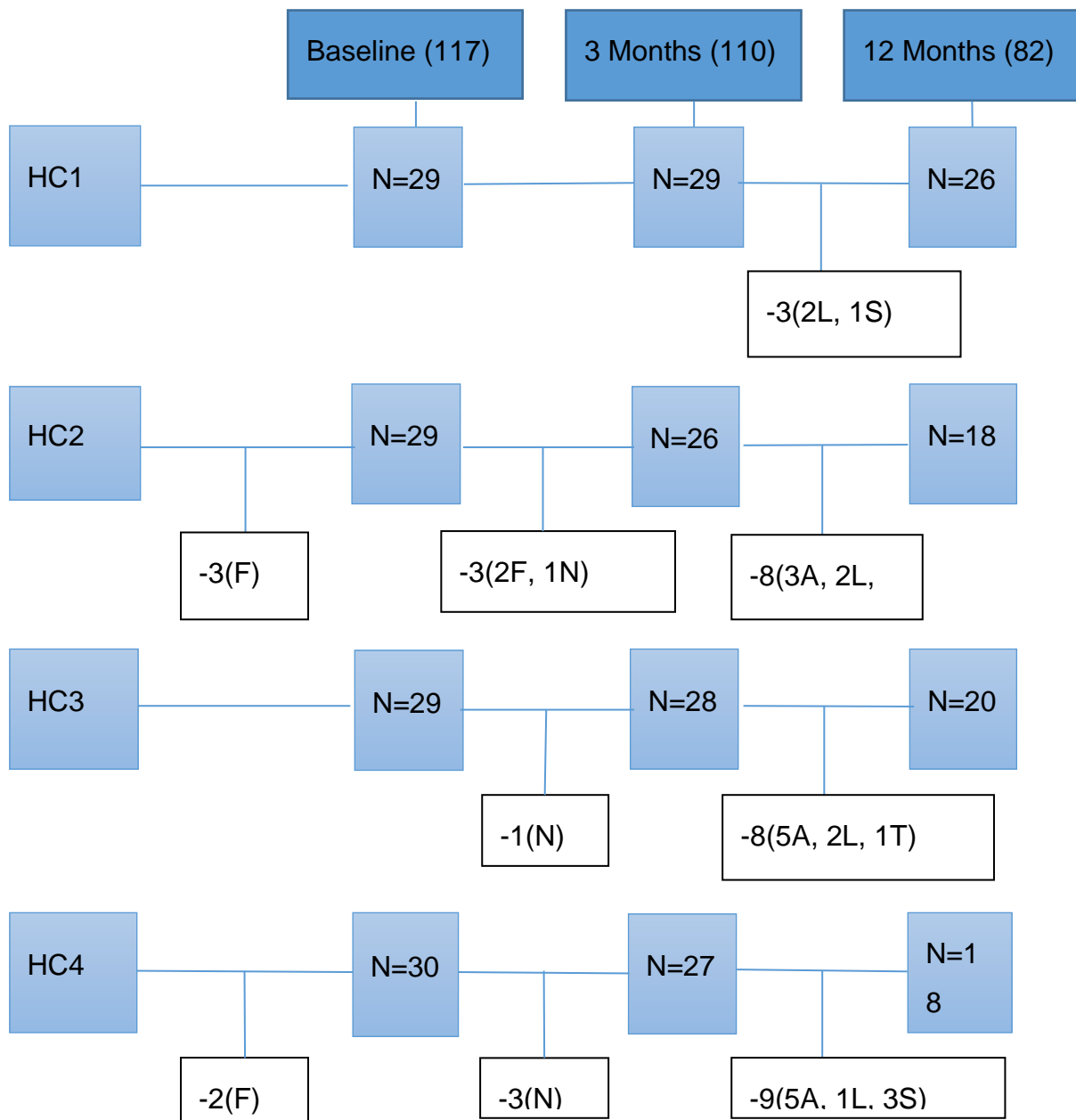
Count (%)	HC1 129(23.8)	HC2 32(26.2)	HC3 29(23.8)	HC4 32(26.2)
Gender				
Male=56(45.9)	14(48.3)	12(37.5)	13(44.8)	17(53.1)
Female=66(54.1)	15(51.7)	20(62.5)	16(55.2)	15(46.9)
Age				

≤44 Years=65(53.3)	15(51.7)	18(56.3)	14(48.3)	18(56.3)
> 44 Years=57(46.7)	14(48.3)	14(43.8)	15(51.7)	14(43.8)
Marital status				
Currently un-married=32(26.2)	9(31.0)	7(21.9)	8(27.6)	8(25.0)
Currently married=90(73.8)	20(69.0)	25(78.1)	21(72.4)	24(75.0)
Education				
Less than or equal to secondary education=62(50.8)	4(13.8)	17(53.1)	20(69.0)	21(65.6)
More than secondary education=60(49.2)	25(86.2)*	15(46.9)	9(31.0)	11(34.4)
Income				
≤1000 OR=70(63.1)	13(44.8)	17(68.0)	22(75.9)	18(64.3)
>1000 OR=41(36.9)	16(55.2)*	8(32.0)	7(24.1)	10(35.7)
Employment				
Currently unemployed=42(34.4)	7(24.1)	13(40.6)	14(48.3)	8(25.0)
Employed=80(65.6)	22(75.9)*	19(59.4)	15(51.7)	24(75.0)
Duration of diabetes				
≤5Years=63(51.6)	17(58.6)*	15(46.9)	10(34.5)	21(65.6)
>5Years=59(48.4)	12(41.4)	17(53.1)	19(65.5)	11(34.3)
Comorbidities				
No comorbidities=27(22.1)	15(51.7)*	6(18.8)	2(6.9)	4(12.5)
With comorbidities=95(77.9)	14(48.3)	26(81.3)	27(93.1)	28(87.5)

\* Characteristics that are potentially atypical in HC1 compared to other health centres

### *Attrition and loss to follow up*

Out of 122 participant who gave consent to participate in the study (the intervention group), 82 completed the 12months follow up (67.2%). Findings indicate that out of 40 participant who dropped out, 32.5% were from the accelerometer group (A), 17.5% reported fear from pain (F), 17,5% lost to follow up (L), 12.5% were not interested (N), 10% were on travel and 10% reported that study was too long (S) (**Error! Reference source not found.**).

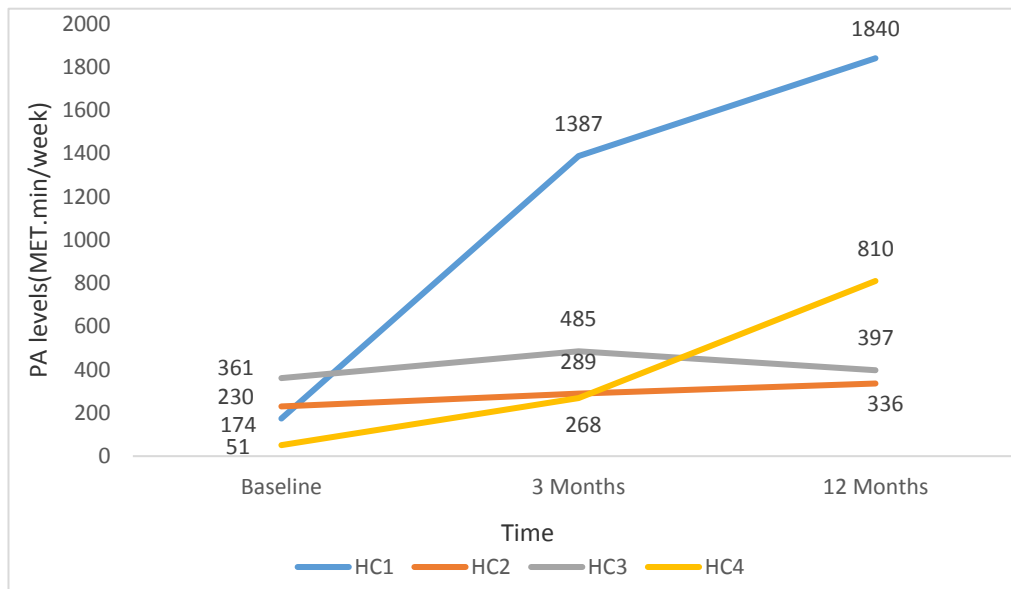


Accelerometer group (A), Fear from pain (F), Lost to follow up (L), Not interested (N), Travel and Study was too long (S).

**Figure 7.8: Recruitment, and retention across the health centres in the intervention group over the study period**

#### Primary and secondary outcomes

At 12 months, It was evident that more than half of the total gain in the PA levels within the intervention group was attributed to participants in HC1 (**Error! Reference source not found.**). The increase in MET.min/week was significantly higher in HC1 compared to: a) HC2 by 1030 ( $P=0.004$ , 95%CI -1727 to -333), b) HC3 by 1443 ( $P<0.001$ , 95%CI -2157 to -729), and c) HC2 by 1504 ( $P<0.001$ , 95%CI -2201 to -807). However, HbA1c seemed to be significantly reduced in HC1 compared to HC3 by -1.1 ( $P=0.003$ , 95%CI -1.7 to -0.4) & 4 by -0.9 ( $P=0.004$ , 95%CI -1.7 to -0.3). Other secondary outcomes across the intervention health centres (HC2, 3, and 4) were not significant when compared to HC1.



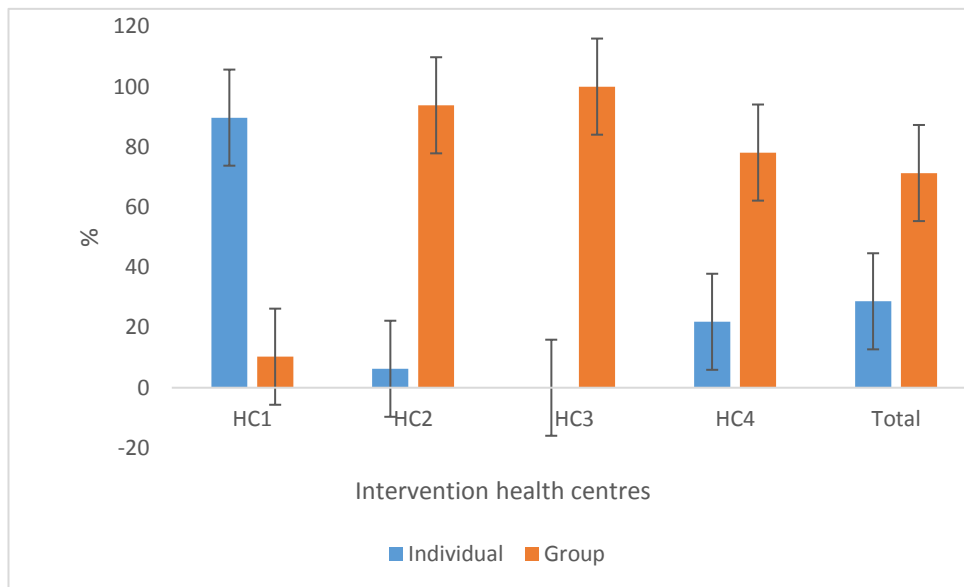
**Figure 7.9: PA levels across the health centres in the intervention group over 12 months**

#### Use of WhatsApp telephone application



Participants were registered in either individual (28.7%) or gender specific group (71.3%) WhatsApp settings. The distribution of WhatsApp use across the health centres within the intervention group is described in **Error! Reference source not found.** All participants of HCs used group WhatsApp vs majority of them in HC1 used individual WhatsApp. Other participants in HC2, and HC4 used the group more than the individual WhatsApp application.

Using a t-test when equal variance is assumed, participants in the individual WhatsApp setting had significantly ( $P < 0.001$ ) higher PA levels compared to those in the group setting at both 3 months [mean (SD) MET.min/week 1305(1643.84) vs 303(451), 95%CI 623 to 1380] and 12 months [2509(3800) vs 307(472), 95%CI 1384 to 3019]. Also, change in PA levels at 3 and 12 months from baseline was greater in the individual vs group WhatsApp intervention group [(+1021, 95%CI 686 to 1358) vs (+2221, 95% CI 1447 to 2997), respectively].



**Figure 7.10: Distribution of WhatsApp use across the intervention health centres**

After the 3 months measurement visit, the only contact between POs and their participants was via WhatsApp monthly messages and active communications. **Error! Reference source not found.** shows the flow of participant within the

WhatsApp individual vs group setting. At week 24 and 36, a few participants moved from group to individual setting while at the end of the project few moved the opposite direction.

**Table 7.6: The total number of people and number of dropping out from the “MOVEdiabetes” WhatsApp communications over 12 months**

Weeks	Individual	Group	Total (dropped out from the WhatsApp communications)
4 weeks (n=117)	35	87	122
8 weeks (n=110)	40	70	110 (-12)
12 weeks	40	60	110
16 weeks	38	57	95 (-15)
20 weeks	38	57	95
24 weeks	40	55	95
28 weeks	38	55	93 (-2)
32 weeks	36	55	91 (-2)
36 weeks	37	54	91
40 weeks	37	50	87 (-4)
44 weeks	37	45	82 (-5)
48 weeks	37	45	82
52 weeks (n=82)	35	47	82

#### 7.4.6 Cost description

The project was funded by the Oman ministry of health and The Research Council (TRC). The training delivered by an external and local PA experts for all POs in the initial set-up phase of the intervention costed 3000 OR (**Error!**

**Reference source not found.**) An additional cost of 4730 OR was used for purchasing the project devices (accelerometers and pedometers from the UK).

**Table 7.7: Resources and cost of delivering the “MOVEdiabetes” intervention**

Item	Description& number	Cost Omani rial (UK £-US \$)*
Training for project team (3 days)	5 days training	3000 (5,950-7800)
Printing study materials	Project materials	2000 (3,960-5200)
Consent forms, information sheets, and intervention materials including questionnaires		
Smart phones	4	400 (795- 1000)
Monthly prepaid phone cards	4	480 (950- 1240)
Pedometers	250	1500 (2,980- 3900)
Accelerometers	30	4,230 (8425-11000)
Total		11610 (23100- 30190)

\*According to exchange rates in April 2019

## 7.5 Discussion

The current study showed that the multi component “MOVEdiabetes” intervention, delivered by trained dietitians, was effective in increasing PA levels in physically inactive adults with T2D within a local diabetes primary care setting at 12 months. The objective accelerometer data also indicated a greater increase in average number of steps/day in the IG. Similarly, objectively measured sitting time was reduced in the IG by -1.5 hours/day more than in the comparison group.

Importantly, despite no significant changes in the metabolic outcomes (weight, BMI and HbA1c), the intervention showed favourable cardio-vascular long-term outcomes (Colberg et al., 2010a) namely in reducing systolic and diastolic blood pressure, and triglycerides at 12 months.

Additionally, results from this part of the thesis analysis indicate the positive effect of the “MOVEdiabetes” intervention on perceived general health, sleep, mental health, pain and responses to quality of life. However, it is important to note that evaluating general wellbeing was not the primary outcome of the “MOVEdiabetes” study. Hence, future similar studies may consider adequately powered designs to elicit between group differences in all the seven dimensions/domains of health (physical, intellectual, emotional, spiritual, social, occupational and environmental) (Hjelm, 2010) although it is important to be wary over participant burden.

Despite positive weak associations, the relationship between change in PA levels and improvements in responses for general health was significant. A greater proportion of those in the IG vs CG perceived improvements in general health (48.4% vs 32.7%) confirming the evidence around effects of PA on general health in patients with T2D (Dunkley et al., 2014, American Diabetes Association, 2013). These results echo the findings reported across various studies on the physical, psychological, mental and rehabilitative benefits of PA (Abdualkarem and Sackville, 2009, Church et al., 2010, Arem et al., 2015).

Sufficient sleep is an integral part in optimum health as it promotes memory consolidation, clearance of brain metabolites, and restoration of nervous, immune, skeletal, and muscular systems (Luyster et al., 2012). Hence, sleep disturbances predispose an individual to cardiovascular disease, metabolic dysfunction, psychiatric disorders, and early mortality (Garfield et al., 2016). Results from the current study highlighted the significant positive effect of the “MOVEdiabetes” intervention on sleep. However, the association between change in PA and sleep was positively significant in the CG and not the IG. These results indicate the need for more research whether PA interventions can

bring about important improvements in duration and quality of sleep in adults with T2D

When the associations with PA levels were explored, feeling downhearted/depressed decreased with the increase in PA levels. This finding is consistent with evidence around PA and mental health in the general population (Biddle, 2016). Overall, associations between change in PA levels and quality of life in adults with T2D, who were reported to require psycho-social care as part of their management (Young-Hyman et al., 2016, Ducat et al., 2014), needs further exploration.

The finding that there were more participants with greater perceived pain in the CG compared to IG indicates that the intervention was helpful in mediating pain and is especially notable since pain was one of the reasons for drop out from the study.

HC1 seemed to have the greatest contribution to the overall PA gained within the intervention group over the study period. However, the health centre analysis was performed on small sample sizes and further work may be needed to confirm this finding. Nevertheless, this could be due to the unique characteristics of the participants from HC1 centre namely higher levels of education, income, employment and lower proportions of comorbidities compared to other interventional health centres. Additionally, all participants in HC1 were using one to one WhatsApp communications with their POs. Results from this study indicate that the use of individual (especially in HC1) vs group setting WhatsApp telephone application had significant effect on increasing PA levels. This finding could be explained by the cultural preferences in one to one communications with health professionals (the POs in this study) and possible stigma of discussing health issues/behaviours with other peers (Abdulhadi et al., 2007). However, in depth analysis of the advantages/disadvantages of WhatsApp use in promoting PA is required including the time/cost implications of monitoring individual vs group Whatsapp communications if rolled out.

### 7.5.1 Strengths of this study

This study makes a significant contribution to the current limited literature on translational research on effective PA interventions internationally and in particular in the Arab world.

The strengths of the current study include the ability of existing health professionals, to extend their roles and deliver the intervention in a clinical setting. Moreover, the use of physiological data from patients' routine electronic medical records enabled the reporting of clinically relevant data.

This is the first trial to utilise accelerometers within the local clinical diabetes setting in Oman. Despite the complexity of data from the accelerometers pertaining to drop out and non-compliance to the 24 hours wear protocol, changes in average steps/day and sitting time were in favour of the IG at 12months. This finding supports the positive effects of the "MOVEdiabetes" intervention on PA levels in the IG vs CG obtained from the self-reported questionnaire.

The intervention used in this trial included support provided via WhatsApp messages. To our knowledge, this is the first study to integrate such technology based approaches as a long term support tool within a PA intervention study in Oman. It is possible that this approach could escalate trust between participants and POs in their respected health centres that facilitated sharing of information, and seeking support and feedback when needed (Abdulhadi et al., 2007). However, a study in Spain reported minor effects from WhatsApp-based interventions to promote PA training compared to face to face interventions (Muntaner-Mas et al., 2017). Therefore, further research is needed on the use of WhatsApp and/or any other texting applications in promoting PA in clinical settings (alone and as part of intervention design).

Notably, similar to other studies, high education (Heiss and Petosa, 2014) and high income (Bauman et al., 2012b) was associated with the long term increase in PA levels within the intervention group. This finding may be linked to greater

awareness of health benefits that could facilitate positive PA behaviour change in higher socioeconomic groups (Kari et al., 2015).

### 7.5.2 Limitations of this study

It should be noted that the trial sample size was calculated on the basis of detecting changes in the self-reported PA questionnaire, not the accelerometers data. Hence, strategies targeting larger sample size could have considered the loss to follow up within the accelerometer group and provided more succinct results on the secondary outcomes of this study. Limitations of the self-reported PA data including the possibility of false reporting (over reporting) cannot be excluded (Dyrstad et al., 2014) indicating instrument bias. Hence, further exploration maybe required to validate the subjective PA measurement tools (GPAQ), investigate reasons for non-adherence and identify ways to improve compliance to accelerometer use.

Importantly, the 53% recruitment rate (232/441) in the current study is less than the predicted rate of 70%. Almost 50% of the approached participants declined participation or missed their appointments. The lower than anticipated rates may not reflect real world/roll out potential because this would not involve the research burden that comes with a study. On the other hand, some people may have been prepared to take part in a study because they consider themselves to be “helping” their medical care givers. It is also possible that those who declined participation may have positively changed their PA behaviour compared to those who actually participated (Brintnall-Karabelas et al., 2011). Hence, findings from this study may not be generalizable.

It is notable that throughout the study period, sitting time was high ( $\geq 10$  hours/day) exceeding the time reported in other studies in Oman (Brazeau et al., 2015a, Mabry et al., 2013). This is an important finding because sitting more than 8h/day increases the risk of all-cause mortality (even among individuals achieving the recommended 150 min/week of PA) (Bell et al., 2014b). It is possible that timing of data collection, population characteristics and cultural

norms may have been different across those studies that have investigated this relationship. As such, interventions to minimise sitting time in this population is required in further studies (Wilmot et al., 2011).

Results from this study indicate a relatively small effect size, however short and long term odds of meeting the PA recommendation of  $\geq 600$  MET.min/week was significantly higher in the intervention vs comparison group (Table 7.3) indicating potential clinical benefits of the “MOVEdiabetes” intervention on general health. Other benefits related to body composition were not explored in this study, however results showed positive effects of the “MOVEdiabetes” intervention on lowering blood pressure and triglyceride levels indicating possible cardio-protective benefits.

The lack of a significant impact on the secondary outcomes namely weight, BMI and HbA1c is not unexpected given the intervention focussed on physical activity alone (because usual care already provided advice on diet or weight management) (Swift et al., 2014, Boule et al., 2001). More importantly, this result may be attributed to limited power to detect an intervention effect. IT should be noted that the study was powered on primary outcomes. Future adequately powered studies are required to better understand the impact of this intervention on secondary outcomes including the biomedical, metabolic and cardiovascular markers but this was not the main purpose of the current research.

Moreover, consistent with the evidence on the dominance of leisure time PA (Arem et al., 2015), results from this study indicated the importance of leisure time activity in the overall increase in PA levels. However, a focus on the other PA domains (work and travel), where inactivity levels are more prominent, may be considered in future studies, especially given that more than half of the participants in both the groups were employed.

Other limitation of this study was its interview based nature where participant may have been influenced to report positive outcomes to their health care providers who interviewed them (respondent bias). However, it might be argued



that complex questionnaires such as the one used in this study, may be better if explained via interviews instead of self-reports. Future studies may equally consider in-depth qualitative approaches (FGDs/interviews) to explore the health outcomes from performing PA in adults with T2D with self-reported responses.

Another limitation is related to the translation and shortening of the general wellbeing questionnaire which may have jeopardised the information needed to explain the health dimensions comprehensively (measurement bias).

Given the evidence on the importance of coping with diabetes (Hernandez-Tejada et al., 2012), it is unfortunate that this study did not investigate the mental health aspects related to possible effects of the intervention on how participants were managing their diabetes (self-care). This would have provided additional evidence on the effect of the “MOVEdiabetes” intervention on diabetes care. Likewise, the effects of participants’ diabetes duration on coping with their diabetes were not included in this study. These areas were omitted to minimise subject burden but should be considered in future PA intervention studies in people with diabetes, whilst being mindful of total participation research burden.

Finally, the results presented in this chapter in regards to general wellbeing need to be interpreted cautiously because the tool used to assess general wellbeing showed poor internal consistency in the current study population indicating the need for more reliable measurement tools in the Arab population.

## **7.6 Conclusion**

The “MOVEdiabetes” intervention was effective in increasing short and long term PA, reducing sitting time and increasing the likelihood of meeting WHO PA recommendations in adults with T2D attending their routine diabetes primary care clinics over 12 month. Additionally, despite no significant impact on weight, BMI and HbA1c, the intervention showed potentially protective cardiovascular

effectiveness namely in reducing blood pressure and triglycerides levels. In addition, the intervention was associated with improvements in wellbeing related to general health, sleep, mental health, pain and quality of life. However, further studies are needed to identify robust tools to measure the multi-dimensions of health/wellbeing for PA interventions in adults with T2D in Arabic speaking countries.

## **Chapter 8 : Perceived changes in physical activity influencers (self-efficacy and social support): findings from the “MOVEdiabetes” study**

### **8.1 Introduction**

Effective interventions are often grounded in a theoretical framework (Avery et al., 2012). The “MOVEdiabetes” intervention (face to face personalised PA consultations, pedometers and monthly WhatsApp messages) was based on the stages of change model, health belief model and social cognitive theory. The three models complemented each other well and served to structure the “MOVEdiabetes” intervention (see Section 3.5.5). These models focused on constructs which are referred to as mechanisms or mediators. In addition, behaviour change techniques (BCTs) (see Section 3.5.6) can help translate theory into practical application. The BCTs incorporated in the “MOVEdiabetes” intervention were drawn from Tudor Locke’s explanation of the effectiveness of pedometers (Tudor-Locke and Lutes, 2009), and from constructs of the theoretical models that are explained within the CALO-RE taxonomy (Michie et al., 2011b). The selected BCTs had been identified as efficient in increasing PA and improving HbA1c in systematic reviews (Avery et al., 2012, Williams and French, 2011, Greaves et al., 2011). The main BCTs applied in the “MOVEdiabetes” intervention included goal setting, action planning, self-monitoring of behaviour, barrier identification, instructions on how to perform a behaviour, use of follow up prompts and social support (see Figure 7.1) (Cradock et al., 2017). Notably, options for social support were integrated within the consultations and WhatsApp communications between the participant and their POs/peers.

However, insights from the literature to the fidelity to the protocol with the respect to BCT delivery and use is limited and the effectiveness of specific BCTs in increasing PA in diabetes care is not fully understood especially in

Arabic speaking countries. Fidelity of each BCT used in the “MOVEdiabetes” intervention was not planned to be measured and thus it may not be possible to contribute to the evidence on the most effective BCTs. However, questions on self-efficacy and social support for PA were included at baseline and 12 months and allow us to examine whether these mediators were improved and consequently whether changes in these were associated with subsequent change to major barriers to PA and indeed subsequent measured PA.

Improving self-efficacy (Gleeson-Kreig, 2006, McAuley, 1993, Oman and King, 1998) and providing options for social support (females in particular) (Lindsay Smith et al., 2017, Trost et al., 2002, Sallis and Hovell, 1990) are important considerations in planning PA interventions as these were identified in the formative work as one of the main barriers to performing PA (see Chapter 4, Section **Error! Reference source not found.**) (Alghafri et al., 2017a). Such approaches are consistent with the psychosocial-ecological model of health behaviour (Sallis et al., 2006), and the behavioural change wheel (BCW) developed by Michie et al. (2011a).

The objective of this chapter is therefore to discuss changes in PA influences, namely self-efficacy and social support in participants of the “MOVEdiabetes” study at 12 months from baseline in regards to:

- Associations between changes in PA levels and self-efficacy and social support
- Changes in self-efficacy and social support across the studied socio-demographic factors (gender, age, education, income and employment).
- The validity and internal consistency of the psycho-social measurement tools used in the “MOVEdiabetes” study.

## 8.2 Methods

A series of English to Arabic translated questionnaires/scales were used to explore perceptions of the “MOVEdiabetes” participants on self-efficacy and social support to PA and changes in the psycho-social outcomes. All original measurement tools (in English) were available online as public documents (Bandura, 1997, Sallis et al., 1987) (see Appendix 8.1 & 8.2). To fulfill the objectives of the “MOVEdiabetes” study, the questionnaires were initially reviewed and modified in English as detailed in section 8.2.1 and 8.2.2 prior to translating them to Arabic language.

The questionnaires were administered to participants of the “MOVEdiabetes” study in the IG and CG at baseline and 12 month follow-up. Data was collected by the POs during the participants’ scheduled visits for collecting the study measurements.

### 8.2.1 The self- efficacy scale (see Appendix 8.1)

The 12-item self-efficacy scale used in this study was primarily informed by the Exercise Self-Efficacy (ESE) scale (Bandura, 1997). The ESE has been shown to be valid and reliable when it has been translated to other languages such as Dutch (van der Heijden et al., 2014), Korean (Shin et al., 2001), Persian (Noroozi et al., 2010) and also Arabic (Darawad et al., 2016). Using factor analysis and internal consistency reliability tests (Cronbach alpha values), all the modified versions of the ESE used in these studies involving diverse population groups reported to have high validity and internal consistency measures including within the Arabic speaking populations in Jordan (Darawad et al., 2016). Due to the anticipated variations in local dialects of the Arabic language across the Arabic speaking countries, re-translating the original English version of the ESE was viewed as more appropriate by the translating company than adapting the Arabic version.

The main interest in the current study was to examine self-efficacy related to the ability to perform PA in the face of barriers to PA. The barriers to PA were based on findings from formative work (Alghafri et al., 2017a) namely lack of willpower, resources and social support. For the 12 questions, participants were asked to rate each one from 0 (no confidence) to 10 (complete confidence) related to his/her current confidence that he/she could perform 150 minutes of moderate to vigorous PA/week. Given there were 12 questions, the total possible score across all the scales ranged from a minimum of 0 to a maximum 120 indicating greater self-confidence.

### 8.2.2 *The social support scale (see Appendix 8.2)*

A modified version of a social support scale by Sallis et al. (1987) was used to determine perceived levels of support. This was a series of 13 questions to enquire about participants' perception of the level of support they received from a) family, and b) friends. Modifications were made to highlight gender sensitive issues related to social support (particularly in females) reflected from the literature search in chapter 3 (see Section 3.4.1), chapter 4 (see Section **Error! Reference source not found.**) and Chapter 5 (see Section 5.4.1). Changes in the scale included extending questions 1 and 2 to include whether they "asked someone to accompany me" and whether family or friends "offered to drive me to the nearest PA facility". Additionally, question 12 pointed out "support to select appropriate PA clothing".

Each item was scored from 0 (no support) to 5 (maximum support). A total sum score of up to 65 was then calculated for family and then friends support independently.

### 8.2.3 *Piloting*

Before full-scale measurements were undertaken, piloting was carried out with 50 participants (with T2D) randomly selected from patient appointment lists at a routine primary care diabetes clinic in one of the health centres in Muscat. The

sample size was calculated based on the average number of patients per day, around 12, and due to complexity of the terminology in the scales it was advised by the statistician to continue sampling until a saturated common understanding was reached. The sampling continued for 5 days.

The average age of the participants in the pilot work was 44.9 (7.9) years, and most were female (64%), and married (90%). Just about third of them completed secondary education (32%), with a moderate income of 500 to < 1000 Omani rials (35%), and employed (36%). The mean duration of diabetes was 7.0 (5.5) years.

The initial construct validity testing for the psycho-social scales were performed using factor analysis. Initial eigenvalues of  $\geq 1.0$  were considered statistically sound to identify any potential factors/components that could be explained/grouped by items/questions within the “MOVEdiabetes” psycho-social scales (Tobias and Carlson, 1969, Dunn et al., 2014). For the self-efficacy scale, factor loadings (for which a desirable magnitude for the item-factor relationships was considered  $\geq 0.3$ ) were significant for 3 components, namely confidence to: a) engage in PA (contained 5 items), b) follow PA plan/instructions (contained 4 items), and c) make time for PA (contained 3 items). This categorisation was used to structure the final version of the self-efficacy scale and was included in the analysis.

Results from the factor analysis in the pilot study population for items in the social support scale had no specific pattern.

Additionally, Cronbach alpha test for internal consistency using SPSS V22 was used. The achieved values were 0.65 and 0.70 indicating ‘questionable’ and ‘acceptable’ internal consistency for both the self-efficacy and social support, respectively (Dunn et al., 2014).

#### 8.2.4 Statistical analysis

For the psycho-social scales used in this trial, scores at baseline and 12 months were described and compared using descriptive statistics and independent sample t-tests. Sum scores were described and trends across the studied socio-demographic characteristics (gender, age, education, income and employment) (see Table 7.1) were explored using Generalized Linear Modelling (GLM). Spearman's correlation test was then used to identify associations between changes in scores from the studied scales with participants' change in reported PA levels (MET.min/week) reported in chapter 7 (see Section 7.4.3). In the correlation analysis, a level of significance less than 0.05 was considered statistically significant.

To estimate the construct validity of the tool in the current population, exploratory factor analysis was used including the 12 items of the self-efficacy scale and the 13 items of the social support scales. The analysis was carried out further to identify factors/components that would potentially explain a minimum of 10% of the variance in the data. Item loadings of more than 0.3 were then identified via principal components analysis with oblique rotation (Tobias and Carlson, 1969). Internal consistency reliability of the "MOVEdiabetes" psycho-social scales was evaluated using Cronbach's Alpha<sup>1</sup> coefficient (Dunn et al., 2014) in SPSS v22 and McDonald's coefficient omega<sup>2</sup> in the free and open source R (R Development Core Team, 2014).

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<sup>1</sup> Alpha coefficient is a value calculated from the pairwise correlations between items in a scale/questionnaire.. A commonly accepted ranges describing internal consistency is as follows: Excellent if  $0.9 \leq \alpha$ , Good if  $0.8 \leq \alpha < 0.9$ , Acceptable if  $0.7 \leq \alpha < 0.8$ , and poor if  $0.6 \leq \alpha < 0.7$

<sup>2</sup> McDonald's omega is an internal consistency reliability coefficient which is similar to Cronbach's Alpha. However, the advantage of Omega has the advantage of taking into account the strength of association between items (factor loadings are allowed to vary in a factor analysis). As a general guideline, threshold values 0.70 is for research purpose, .90 for clinical or important decisions.



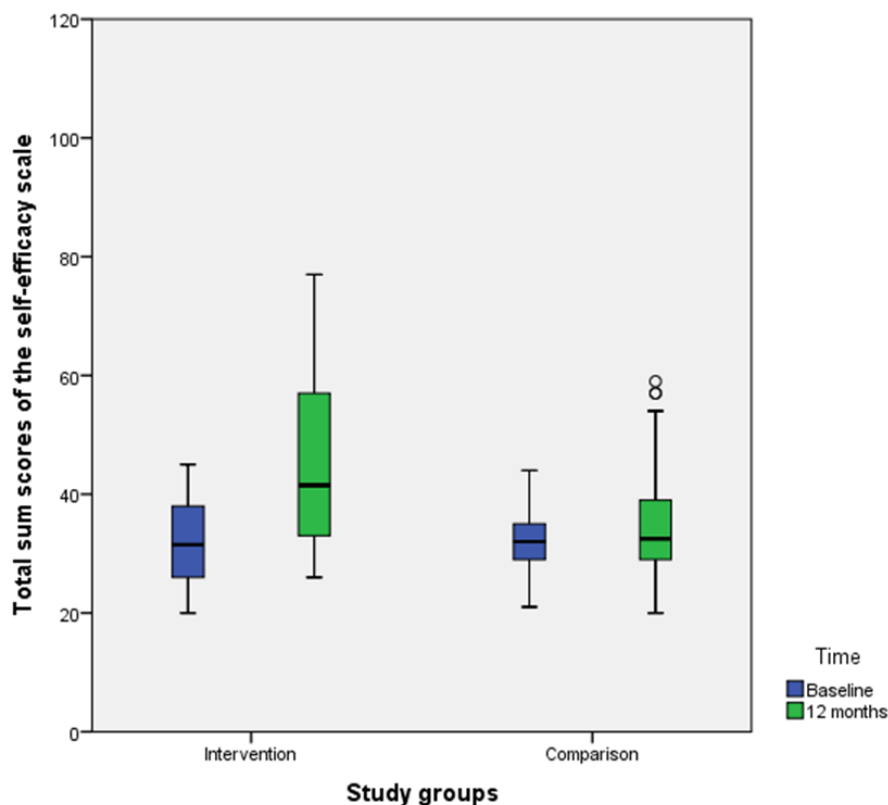
### 8.3 Results

The populations' socio-demographic and physiological characteristics are described in Chapter 7 : , Section 7.4.2.

#### 8.3.1 *Results of change in self-efficacy scale*

##### *Descriptive statistics*

Using a t-test of two independent samples, mean (SD) sum scores of the self-efficacy scale were comparable at baseline [32.3 (6.7), 95%CI 31.1-33.5 vs 31.9 (4.6), 95%CI 31.0-32.8 in the IG and CG respectively,  $P=0.58$ ] (Figure 10.1), but significantly higher in the IG vs CG at 12 months [45.7 (13.8), 95%CI 43.2-48.2 vs 34.8 (8.7), 95%CI 33.2-36.5,  $P<0.001$ ] (**Error! Reference source not found.**).



t-test of two independent samples,  $P=0.58$  at baseline and  $P<0.001$  at 12 months

**Figure 8.1: Between the study groups (intervention group n=122, comparison group n=110) sum scores of the self-efficacy scale at baseline and 12 months.**

*Univariate and multivariate analysis*

Univariate analysis using GLM showed a significantly greater increase in mean self-efficacy scores in the IG than CG at 12 months, by +10.9 ( $P < 0.001$ , 95%CI 7.1 to 13.5).

Multivariate analysis which included the studied socio-demographic variables showed a significantly greater increase in total sum scores of the mean self-efficacy scale in IG participants without comorbidities compared with IG participants with comorbidities by +12.2 (95%CI 6.8 to 17.6,  $P < 0.001$ ), and in those with higher income compared with those with lower income by + 9.7 (95%CI 5.2 to 14.2,  $P < 0.001$ ). Gender was the only factor which influenced the increase in sum score within the CG. Males (as compared to females), had significantly higher change in sum score between baseline and 12 months by +4.2 (95%CI 0.5 to 7.9,  $P = 0.02$ ).

Participants' change in scores on the self-efficacy scale at 12 months from baseline were tested for association with their reported change in PA levels (MET.min/week). Results showed a positive significant, but weak association at the total population level and within the IG only ( $r = 0.30$  and  $r = 0.41$   $P < 0.001$ ).

The total scores for self-efficacy were then categorised across the three factors identified in the pilot stage (see Section 8.2.3). **Error! Reference source not found.** illustrates the increase in mean self-efficacy scores in confidence to engage with PA, follow PA instruction and manage time in the study groups. The contribution of scores from questions related to engagement with PA (5 questions) to the overall total self-efficacy sum scores was higher than that from the other categories.

**Table 8.1: Between study group differences in self-efficacy sum scores at 12 months study follow up**

Self-efficacy categories	Intervention group n=122			Comparison group n=110			Between group difference, (95% CI), P value
	Baseline	12 months	Differences from baseline	Baseline	12 months	Differences from baseline	
Engagement to PA	11.8(5.0)	19.3(5.3)	7.6(6.7)	11.0(2.6)	14.4(2.9)	3.4(4.3)	+4.2, (2.7 to 5.7) P<0.001
Follow PA instructions	11.8(2.4)	14.8(6.2)	3.0(6.3)	11.4(2.2)	11.7(4.0)	0.2(5.0)	+2.9, (1.4 to 4.4) P<0.001
Manage time	8.9(2.4)	11.6(5.5)	2.8(6.6)	9.2(2.1)	8.8(3.7)	0.4 (2.1)	+3.2, (1.7 to 4.6) P<0.001
Total	32.4(5.9)	45.7(13.8)	13.3(13.7)	31.8(4.3)	34.8(8.7)	3.0(10.9)	+10.3, (7.1 to 13.5) P<0.001

*Validity and internal consistency (see Appendix 8.3)*

The construct validity of the “MOVEdiabetes” self-efficacy scale was tested using exploratory factor analysis at both baseline and 12 months. Based on factor loadings, results showed the suitability of all the 12 items/questions in the questionnaire within this study population. Consistent with the categorisation within the “MOVEdiabetes” self-efficacy scale in the piloting phase (see Section 8.2.2), three factors/components namely confidence to: engage with PA, follow PA instructions and manage time, were similarly identified at both baseline and 12 months.

The inter-item correlations were also evaluated, which ranged from  $r = -0.1$  to  $0.9$  at baseline and  $r = -0.2$  to  $0.8$  at 12 months. The highest inter-item correlation at baseline was noted among Items/questions 2 (How confident are you that you can engage in PA when you are in a bad mood?) and 3 (How confident are you that you can engage in PA when you feel you don't have time?) ( $r = 0.7$ ). High correlations were also identified between items 2 and 4 (How confident are you that you can engage in PA during bad weather?) ( $r = 0.9$ ). Similarly, at 12 months correlations were noted between items 6 (How confident are you that you can follow PA directions from an instructor?) and 7 (How confident are you that you can pace yourself during the activity to avoid overexertion?) ( $r = 0.8$ ) and items 7 and 10 (How confident are you to arrange your schedule to perform PA regularly no matter what?) ( $r = 0.8$ ). The cross-contribution from these questions indicate that they were very similar and participants may have had self-efficacy levels that had similar impact on these questions.

At baseline and 12 months, values from the Cronbach's alpha test (Dunn et al., 2014) were  $0.79$  and  $0.82$  and Omega test showed values of  $0.79$  and  $0.88$  respectively. These values indicate good internal consistency reliability of the scale in this study population.

### 8.3.2 Data from the social support scale

#### *Descriptive statistics*

Overall, the perceived scores for social support from family were higher than those for support from friends in both the study groups (Table 8.2). Total scores for social support from both family and friends increased at 12 months from baseline for both the study groups.

#### *Univariate and multivariate analysis*

The between group difference in changes in scores was in favour for the IG, being significant for social support from friends only [+2.3 (95%CI 1.1 to 3.7,  $P<0.001$ )] (**Error! Reference source not found.**).

Participants' changes in total scores on the social support scales at 12 months from baseline were analysed to determine whether there was any association with the change in the reported PA levels (MET.min/week). Results showed no significant association between support from either family or friends and PA levels. Similarly, results from multivariate analysis of changes in the social support scores across the studied socio-demographic factors were not significant.

#### *Validity and internal consistency*

#### **Family social support (see Appendix 8.4)**

Factor analysis included the 13 items/questions from the family social support scale. Six factors were identified that significantly explained the maximum variance in the data at both baseline and 12 months.

Inter-item correlations ranged from  $r=-0.1$  to  $0.4$  at baseline and  $r=-0.2$  to  $0.7$  at 12 months. No high interactions (above  $0.7$ ) were identified indicating that there was no significant interaction between responses to the items in the scale. Results from the Cronbach's alpha revealed a value of  $0.59$  and  $0.82$  and

Omega scores were 0.38 and 0.61 at baseline and 12 months, respectively, indicating reasonable internal consistency at 12 months only.

**Table 8.2: Between study group differences in mean change in scores for social support from family and friends (SD)**

Components of social support	Intervention group			Comparison group			Between group difference in change in social support	
	Baseline	12 months	Difference from baseline	Baseline	12 months	Difference from baseline	Mean (95%CI), P value	
Family social support	13.5(4.5)	16.1(4.5)	+2.6(6.4)	10.5(3.5)	12.0(5.3)	+1.4(6.3)	+1.2 (-0.4 to 2.8)	+2.3 (1.1 to 3.7)
Friend social support	9.5(2.8)	12.2(5.1)	+2.7(6.0)	9.2(3.1)	9.6(3.0)	+0.4(4.2)	0.1	<0.001

### **Friend social support (see Appendix 8.5)**

At 12 months, all items/questions in the PA social support scale were retained in the factor analysis except two items/questions: Q3 (Gave me helpful reminders to exercise) & 4 (Gave me encouragement to stick with my exercise program). Seven factors and five factors were identified, at baseline and 12 months, respectively, which were inconsistent with the categorisation proposed in the social support scale by Sallis et al. (1987).

The inter-item correlations ranged from  $r=-0.01$  to  $0.5$  at baseline and  $r=-0.08$  to  $0.6$  at 12 months. No high interactions (above  $0.70$ ) were identified.

Values of  $0.20$  and  $0.40$  were obtained using Cronbach's alpha and  $0.40$  and  $0.50$  using Omega testing at baseline and 12 months, respectively, indicating poor internal consistency of this scale in this population.

## **8.4 Discussion**

This is the first study in Oman that has reported measures of psycho-social aspects of health in a PA intervention study. Self-efficacy defined as "one's ability to meet activity goals, despite barriers" (see Chapter 3, Section 3.5.5) has been reported in several studies to be a strong predictor for performing and adhering to PA across varying populations including adults with T2D (Resnick et al., 2000).

Similar to findings from other studies (Darawad et al., 2016), results from the current study showed an increase in self-efficacy scores in participants of both the study groups (IG and CG) at 12 months from baseline. However, this increase was significantly greater in the IG. This increase was (although weak) positively correlated with participants' changes in PA levels.

Within the IG, absence of comorbidities and high income were positively associated with higher changes in self-efficacy scores at 12 months from baseline. The reasons for this could be due to better health status which is more likely to enhance one's self confidence and ability to perform more intense PA



(Williams and French, 2011). Higher income may be associated with better PA opportunities including greater purchasing capacity for resources such as pedometers, watches, treadmills, gym memberships or clothing that could facilitate positive PA behaviour change (Kari et al., 2015, Bauman et al., 2012b). These results highlight the importance of considering low cost options when planning PA interventions for health benefits to ensure equity of access across the socio-demographic profile of the population (Hernandez et al., 2013, Kari et al., 2015). Consistent with other studies (Heiss and Petosa, 2014, Mabry et al., 2013), gender was the only positive correlate for the increase in self-efficacy sum scores within the CG, with males reporting greater increase in scores at 12 months from baseline. This suggests that gender specific approaches may be needed to achieve improvements self-efficacy in PA specifically for females (see Chapter 4, Section **Error! Reference source not found.**). Such approaches could include safe and closed gender specific PA facilities that could offer care for children.

Effective techniques for enhancing self-efficacy for PA were described in a review by Williams and French (2011) including “action planning”, “providing instructions” and “effort reinforcement”. In the current study, the face to face personalised PA consultations were designed to include these self-efficacy enhancing techniques namely goal setting, action planning, self-monitoring of behaviour, barrier identification, instructions on how to perform a behaviour, use of follow up prompts and social support (see Figure 7.1) (Alghafri et al., 2017d). Questions related to engagement to PA had the highest contribution to the overall self-efficacy sum score in both the study groups. Further exploration may be useful to ensure strategies that resulted in achieving high PA engagement are continued, but also need to consider how to address the other less reported PA self-efficacy factors related to following PA instructions and managing time for PA.

However, evaluating the effectiveness of these techniques for changing PA self-efficacy and PA behaviour is beyond the scope of this study. Further studies are needed to confirm the findings of this study and develop culturally suitable ways to enhance PA self-efficacy in adults with T2D.

Additionally, despite the weak correlation between self-efficacy sum scores and perceived PA levels, it is acceptable to conclude that the results from this study support the utilization of this measurement tool for PA self-efficacy in adults with T2D. However, objective PA measurement is required to validate the finding that “more active people score higher on Exercise Self-Efficacy (ESE) scales” (Everett et al., 2009, Darawad et al., 2016).

A number of studies have highlighted the importance of social support in initiating and/or maintaining PA behaviour change (Rosenstock et al., 1988, Jennifer Gristwood, 2011, Bandura, 2001, Barrera et al., 2008, Plotnikoff et al., 2010c). WHO defines social support as being both ‘emotional and practical support characterising good social relations’ and a social determinant of health (van Dam et al., 2005, World Health Organization, 2003). Social support for PA can be instrumental (e.g. helping with transportation or giving PA devices); informational (e.g. telling about PA resources); emotional (e.g. asking about how the performed PA is going on); or appraisal (e.g. providing encouragement or reinforcement) (Lindsay Smith et al., 2017). In this study, participants in the IG were encouraged to attend their scheduled personalised PA consultations with a family member or a friend (see Chapter 6).

Changes in family social support were not significantly different between the study groups. This is a different finding from the limited research in this area (Lindsay Smith et al., 2017). This finding perhaps may not be surprising given the strong cultural value for family support across populations in the Arab and Muslim world (Crescent of Care, 2009, Benjamin and Donnelly, 2013). This is supported by the fact that the majority of the study population were married indicating that the majority were potentially advantaged with social support from family (Benjamin and Donnelly, 2013). Future studies could usefully explore ways to use family support in PA promotion.

On the contrary, the significant between group differences between baseline and 12 months follow up in social support from friends suggest that participants in the current study appreciated the continuous support/feedback from POs and/or peer participants through the WhatsApp phone application (see Chapter 7, Section 7.3.7). Despite evidence on the positive effect of peers/buddy

support in lifestyle interventions (Ginis et al., 2013), there is limited information available on the effects of peer support from phone applications (including texting) vs support from HPs on promoting PA in diabetes care. This could be included in future research.

Compared to findings from the literature on the positive effects of social support on PA levels (Lindsay Smith et al., 2017), there was no significant association between reported PA levels (MET.min/week) and level of perceived support for either family or friends in this study. Reasons for the lack of an association between PA levels and social support, despite the use of WhatsApp in this study, needs further evaluation. This could be a valid finding, or it may be linked to limitations related to the complexity of the questionnaire (measurement bias) as there is no evidence on validity of this scale within the Arabic speaking countries. This finding was supported by the relatively poor internal consistency value for social support from friends (Cronbach's alpha value 0.20 & 0.40 and Omega values of 0.40 & 0.50 at baseline and 12 months respectively).

Additionally, levels of PA in this study were subjectively measured using GPAQ across the PA domains indicating possible recall bias explained earlier in section 7.5.2. Future social support for PA could consider options for a supportive environment across all PA domains (work, travel and leisure). This could include social activities at work places such as group walking in break times or walking meetings. However, this concept needs to be explored further using more in-depth and culturally relevant assessments on the type, frequency and sources of support for example, family, friend, spouse, children, health care provider, occupational health departments and other organisations.

## **8.5 Conclusion**

Despite more positive changes in the psycho-social scales namely self-efficacy and social support from friends within the IG vs CG of the "MOVEdiabetes" study, these changes were not associated with greater changes in PA.

Further investigation is needed as to why scores for social support were not significantly associated with PA levels given the use of the WhatsApp approach.

Results from the internal consistency test for the measurement tools used in this study population was supportive for using the current self-efficacy scale and not the social support scale. Further studies are needed to identify robust tools to measure social support for PA in culturally bounded Arabic speaking countries.

## Chapter 9 : Acceptability of the “MOVEdiabetes” study

### 9.1 Introduction

Despite the strong evidence base for PA and the management of diabetes (Colberg et al., 2016) (see Section 3.2.1), the majority of PA interventions have been performed in a controlled research setting, using resource intensive methods, of short duration and limited long-term follow-up (Matthews et al., 2014b). Minimal information is available on how acceptable these interventions are when adapted and implemented within everyday practice (van Sluijs et al., 2004).

The use of process evaluations to guide the comprehension and translation of research findings for effective clinical practice is increasing. However, a lack of consistent reporting of the evaluation findings remains an issue (Grant et al., 2013, Matthews L., 2013).

Despite the reported barriers to promoting PA in clinical settings such as a lack of time, training and assessment tools (see Section 55.4.1), some methods to facilitate and support behavioural changes regarding PA in primary care have proven to be effective in several studies in the West (Matthews et al., 2017, Avery et al., 2016, Kirk et al., 2009). However, to address cultural, social and clinical differences, it is important to evaluate the acceptability and appropriateness of transferring evidence from the West to the Arab world.

This chapter aims to describe reflections from the participants in the intervention group and all the POs of the “MOVEdiabetes” study in order to establish if the “MOVEdiabetes” study was acceptable. Acceptability in this evaluation included questions on satisfaction, appropriateness and suitability of the “MOVEdiabetes” study overall and its intervention components (PA consultations, use of pedometers and Whats App). Questions to assess adherence to intervention delivery were also included.

## 9.2 Methods

### 9.2.1 *Measures/assessment instruments*

Two questionnaires guided by Linnan and Steckler (2002) were developed to assess intervention group participants' and POs' perceived acceptability of the programme. The responses to the questions (11 from the participants and 8 from the POs exit surveys) were ordinal and designed on a five point Likert scale (Table 9.1 and Table 9.2). Additionally, open ended questions, detailed later, were included to explore perceptions from the participants and POs on required information, challenges and general comments. The surveys were both developed for use on completion of the trial (exit survey).

To maximise content validity for item selections, the revision process of the questionnaires involved assessment by the external supervisors of this project and two independent PA researchers from Oman and a subsequent revision in light of their feedback. Prior to field administration, an internal pilot testing with a convenient sample of adults with T2D (n=10) was carried out. Minor changes were made to ease understanding of the questions including re-organising the questions and responses.

#### *Participants' exit survey (see Appendix 9.1)*

The 11 item survey was an interviewer-led questionnaire and administered to the intervention group participants. The items explored overall satisfaction of the project (from very dissatisfied to very satisfied), if information received regarding the project was enough (from too little to too much information), if they had enough opportunities to ask questions (from not at all to very often) and if answers to their questions were satisfactory (from not at all to completely). Additionally, the survey included questions on the likelihood of recommending the intervention to others (from very unlikely to very likely), accessibility to the health centres (from very difficult to very easy), and if the intervention was appropriate in diabetes care (from not at all appropriate to very appropriate).

Participants were also asked if they perceived their PA behaviour change to be acceptable (from not at all to very acceptable).

To follow, participants were asked to rate each intervention component (face to face consultations, pedometers and use of WhatsApp) from a range of five options from very poor to very good (see Table 9.1). The consultations were rated for their content, relevance, duration and frequency. Pedometers on the other hand were rated for length of the device use, importance to diabetes care, longevity, and usefulness. Finally, WhatsApp communications were rated for their content, relevance, time required, frequency of messages, and supportiveness.

Four open ended questions queried participants' perceptions of: a) aspects of the project where more information was needed, b) challenges of taking part in the project, c) barriers to increasing physical activity behaviour, and d) general comments.

An independent nurse/researcher interviewed the participants who completed their 12 months study (n=82) follow up and recorded their responses.

*Project officers' exit survey (see Appendix 9.2)*

A self-reported 8-item (five point Likert scale) based questionnaire was completed by all POs at the end of the "MOVEdiabetes" study. Questions included overall satisfaction with the intervention (from very dissatisfied to very satisfied), if training received prior to the intervention delivery was enough (from far too little to far too much), if they had opportunities to ask questions (from not at all to very often) and if the answers to their questions were satisfactory (from not at all to completely). An additional question was included on the appropriateness of the intervention in diabetes care (from not at all appropriate to very appropriate). Also, individual components of the "MOVEdiabetes" intervention were rated (from very poor to very good) by POs in terms of content, relevance, and frequency of the PA consultations. For use of pedometers, ratings were on their usefulness and relevance. WhatsApp communications on the other hand, were rated for content, relevance, time required and frequency of messages. Finally, a general question on the

suitability of each of the intervention components in diabetes care was included (not at all suitable to very suitable).

In the open ended questions of the survey, POs were asked to document their perceptions on topics which required more information, challenges to delivering the intervention, and if they had any comments.

#### *Fidelity monitoring and assessment*

Short meetings were carried out in the last week of every month between the PI and POs in their respected health centres to discuss attendance sheets, issues with the PA consultations, and participant appointment slots. Every effort was made to give the participants convenient appointments and reschedule appointments when needed. Additionally, the smart phones (specific for the “MOVEdiabetes” study) in the intervention health centres facilitated the communication between the POs and PI. The WhatsApp telephone application (in addition to its use for intervention purposes) and phone calls were used throughout the study period to manage the daily logistics and administrative queries.

In order to assess adherence to intervention delivery, an external assessor/observer (independent nurse) audited 10% of randomly selected PA consultation notes using specific “MOVEdiabetes” check lists (see Appendix 9.3). The 20 item check list was developed to rate every item of the PA consultation from a scale of 1 (not done), 2 (partially done) and 3 (completely done) (see Appendix 9.3). Total scores therefore ranged from 20-60.

#### *Analysis*

Mixed methods were used to analyse data on acceptability:

##### *Quantitative*

Frequency tables were used to get the response proportions (%) along all items in the questionnaires using IBM SPSS Statistics for Windows (V 22).

##### *Qualitative*



Given that the questionnaire was interviewer led, the open ended questionnaire responses were transcribed verbatim (see Appendix 9.4 and 9.5) and analysed using thematic content analysis (Virginia & Victoria, 2013). Initial responses were read several times by the principal investigator (TSA) followed by open coding, grouping and categorizing data according to emerging themes. A coding scheme was then developed based on the major recurring themes. Themes were cross-checked by another independent researcher (SA) and areas of contradiction were discussed and adjusted. A final revision was carried out by the local project supervisor (YF) as a further measure of inter-rater reliability.

### **9.3 Results**

#### **9.3.1 Participant exit survey**

All participants in the IG who completed the 12 months visit (n=82) responded to the exit questionnaire (38 male, 44 female) (Table 9.1).

##### *Overall satisfaction*

The vast majority of participants were 'very satisfied' (42.7%) or 'quite satisfied' (43.9%) with the project. Only 9% were not sure and very few were 'quite dissatisfied' (2.4%).

##### *Information received and feedback*

Most felt the information received was 'more than necessary' or 'sufficient information' (43.9% and 29.3%, respectively) whereas a fifth of the participants thought it was 'far too much' (18.7%). The remaining participants (8.5%) did not feel they received enough information and 'far too little' information.

The majority of participants reported that they 'very often' had the opportunity to ask questions (76.8%), the remainder describing this as 'sometimes' (20.7%), or 'every once in a while' (2.4%).

Most participants were 'completely' or 'sometimes' satisfied with answers (32% and 53.4%, respectively), and a few were satisfied 'every once in a while' or 'rarely satisfied' (13.4% and 1.2%, respectively).

#### *Recommendation to others*

Two thirds indicated they were likely to recommend the project to others (54% 'very likely', 12% 'quite likely'), with the remainder mostly unsure (23%) and few were 'very unlikely' (11%) to recommend it to others.

#### *Ease of access to the health centre*

Most perceived coming to the health centre as very easy (54.9%) or quite easy (34.1%). Only 1.2% perceived coming to the health centre as quite difficult.

#### *Perceptions of appropriateness in diabetes care*

Most participant perceived the project as 'very appropriate' and 'quite appropriate' within local diabetes primary care (59.8% and 25.6% respectively). Other responses were 'unsure' (12.2%) or 'quite inappropriate' (2.4%).

#### *Perceptions of PA behaviour change*

Most participants perceived their PA behaviour to have changed, 32% 'to a great extent' and 36.6% 'somewhat'. The remainder were 'not sure' (17%) or experienced 'very little' (11%) or 'no change' (2.4%).

#### *Perceptions on intervention components*

Except for use of pedometers (length of device use), no one responded 'poor' or 'very poor' to any of the other Intervention components.

Content, relevance, duration of the PA consultations and frequency were all perceived as 'good' to 'very good' by most of the participants (86.6%, 95.0%, 96.3%, and 97.6% respectively).

Despite the fact that less than half of the participants (48.8%) reported the longevity of the pedometers to be 'good' to 'very good', most participants

perceived their relevance to diabetes management, wearing them and usefulness as 'good' to 'very good' (81.7%, 81.7% and 92.7% respectively).

The content, relevance, time required, frequency and supportiveness of WhatsApp monthly messages were all perceived as 'fairly good' to 'very good' by the majority of the participants (89.1%, 92.7%, 89.1%, 96.4% and 98.8% respectively).

**Table 9.1: Participants' responses to the exit survey (completed 12 months follow up n=82)**

Questions	Responses n(%)				
Overall, how satisfied were you with the "MOVEdiabetes" project?	Very dissatisfied	Quite dissatisfied	Neither satisfied nor dissatisfied	Quite satisfied	Very satisfied
	0	2(2.4)	9(11)	36(43.9)	35(42.7)
Do you feel you received enough information about the project at the start?	Far too little	Not enough	Sufficient information	More information than was necessary	Far too much information
	2(2.4)	5(6.1)	24(29.3)	36(43.9)	15(18.3)
Did you have enough opportunity to ask questions during the project?	Not at all	Rarely	Every once in a while	Sometimes	Very often
	0	0	2(2.4)	17(20.7)	63(76.8)
Were your questions answered to your satisfaction?	Not at all	Rarely	Every once in a while	Sometimes	Yes, completely
	0	1(1.2)	11(13.4)	44(53.4)	26(31.7)

How likely are you to recommend "MOVEdiabetes" to other people?	Very unlikely	Quite unlikely	Neither likely nor unlikely	Quite likely	Very likely
	0	9(11)	18(23)	10(12)	45(54)
How did you find coming up to the health centre for your appointments?	Very difficult	Quite difficult	Neither easy nor difficult	Quite easy	Very easy
	0	1(1.2)	8(9.8)	28(34.1)	45(54.9)
Having taken part, do you think this program is appropriate in diabetes care?	No, not at all appropriate	Quite inappropriate	Neither appropriate or inappropriate	Quite appropriate	Very appropriate
	0	2(2.4)	10(12.2)	21(25.6)	49(59.8)
Is your change in physical activity behaviour acceptable?	No change, not at all	Very Little change	Not sure	Somewhat	To a great extent
	2(2.4)	9(11)	14(17)	30(36.6)	27(32.9)
Please rate the consultations you received	Very poor	Poor	Acceptable	Good	Very good
Content	0	0	11(13.4)	24(29.3)	47(57.3)
Relevance	0	0	4(4.9)	15(18.3)	63(76.8)
Duration per consultation	0	0	3(3.7)	7(8.5)	72(87.8)

Frequency	0	0	2(2.4)	15(18.3)	65(79.3)
Please rate using pedometers	Very poor	Poor	Neither poor nor good	Fairly good	Very good
*Length of device use	6(7.3)	16(19.5)	20(24.4)	11(13.4)	29(35.4)
Importance to diabetes management	0	0	15(18.3)	21(25.6)	46(56.1)
Wearing it (putting on and off)	0	0	15(18.3)	17(20.7)	50(61)
Usefulness	0	0	6(7.3)	14(17.1)	62(75.6)
Please rate the WhatsApp communication you received	Very poor	Poor	Neither poor nor good	Fairly good	Very good
Content	0	0	9(11)	3(3.7)	70(85.4)
Relevance	0	0	6(7.3)	4(4.9)	72(87.8)
Time required	0	0	9(11)	13(15.9)	60(73.2)
Frequency of messages	0	0	3(3.7)	13(15.9)	66(80.5)
Supportiveness	0	0	1(1.2)	11(13.4)	70(85.4)

\* The Arabic translation implied on how long the pedometer lasted

### 9.3.2 Project officers' exit survey

Sixteen POs participated (2 male vs 14 female) in intervention delivery (the consultations were delivered by the dietitians only) and data collection across the 8 randomly selected health centres: 8 doctors, 4 nurses and 4 dietitians (Table 9.2).

#### *Overall Satisfaction*

All POs were either 'very satisfied' (n=13) or 'quite satisfied' with the project (n=3).

#### *Perceptions on the training received*

Apart from three POs who perceived the training as having 'far too much' and 'more information than was necessary', ten POs thought that the training had 'sufficient information'.

#### *Opportunity for asking questions and feedback*

Opportunity to ask questions was rated as 'very often' by 14 POs and 'sometimes' by only two POs. Answers were perceived as 'completely' satisfactory by ten of the POs vs 'sometimes' satisfactory by 6 of them.

#### *Participants' ratings for the intervention components*

All the dietitians (n=4) who delivered the face to face personalised PA consultations perceived the consultations as 'very good' for content, relevance and frequency. Additionally, All POs perceived the pedometers as useful and relevant to diabetes management.

Content, relevance, and time required for activation of pedometers was perceived as 'very good' by all the 16 POs. Thirteen POs perceived the

frequency of Whatsapp messages as 'very good' while the remaining three thought they were fairly good.

*Appropriateness and suitability of the overall intervention and its components in diabetes care*

Overall POs perceived the intervention as 'very appropriate' (14) or 'quite appropriate' (2).

Suitability of all the "MOVEdiabetes" intervention components were perceived as 'quite' to 'very suitable' with no negative or neutral responses.



**Table 9.2: Project officers' perceptions on questions of the exit survey (n=16)**

Questions	Responses				
	Very dissatisfied	Quite dissatisfied	Neither satisfied nor dissatisfied	Quite satisfied	Very satisfied
Overall, how satisfied were you with the "MOVEdiabetes" project?	0	0	0	3(18.8)	13(81.2)
Do you feel you received enough training about the project at the start?	Far too little	Not enough information	Sufficient information	More information than was necessary	Far too much information
	0	0	10(62.5)	3(18.8)	3(18.8)
Did you have enough opportunity to ask questions during the project?	Not at all	Rarely	Every once in a while	Sometimes	Very often
	0	0	0	2(12.5)	14(87.5)
Were your questions answered to your satisfaction?	Not at all	Rarely	Every once in a while	Sometimes	Yes, completely
	0	0	0	6(37.5)	10(62.5)
Please rate the consultations you conducted*	Very poor	Poor	Acceptable	Good	Very good
Content	0	0	0	0	4(100)

Relevance	0	0	0	0	4(100)
Frequency	0	0	0	0	4(100)
Please rate the use of pedometers as physical activity self-monitoring tool	Very poor	Poor	Acceptable	Good	Very good
Usefulness	0	0	0	0	16(100)
Relevance to diabetes management	0	0	0	0	16(100)
Please rate the WhatsApp communication you were involved in	Very poor	Poor	Acceptable	Good	Very good
Content	0	0	0	0	16(100)
Relevance	0	0	0	0	16(100)
Time required	0	0	0	0	16(100)
Frequency of messages	0	0	0	3(18.8)	13(81.3)
Having taken part, do you think this programme is appropriate/suitable in diabetes primary care?	Not at all appropriate/suitable	Not very appropriate/suitable	Not sure	Quite appropriate/suitable	Very appropriate/suitable
The "MOVEdiabetes" study overall	0	0	0	2(12.5)	14(87.5)
Consultations	0	0	0	3(18.8)	13(81.3)

Pedometers	0	0	0	5(31.3)	11(68.8)
Personal PA diaries	0	0	0	4(25)	12(75)
WhatsApp	0	0	0	6(37.5)	10(62.5)

\* The face to face personalised PA consultations were all carried out by the dietitians only

### 9.3.1 Responses to the open questions

#### *Responses from the **participants***

More than half of the participants did not provide responses to the open questions in the questionnaire (see Appendix 11.4).

#### **Aspects of the project where more information was needed (46/82 responders)**

Overall, participants expressed an interest in knowing more about types of exercises, the use of accelerometers and PA options in the presence of comorbidities with questions such as:

*What type of exercise is suitable for patients with diabetes? P\_HC1*

*What is the purpose of the accelerometers? P\_HC1*

*I have glaucoma, can I exercise? P\_HC2*

#### **Challenges of taking part in this project (21/82 responders)**

Two main themes were identified for challenges of taking part in the project: long and exhausting measurement tools and lack of time for intervention delivery:

*The questionnaires are too long and time consuming P\_HC4*

*I don't have time to attend the PA consultations P\_HC2*

#### **Barriers to increasing physical activity behaviour (36/82 responders)**

Hot weather, lack of time, resources and pain were the main themes identified as barriers to increasing PA behaviour (illustrated below):

*It is too hot outside, I can't walk P\_HC4*

*I have no time for physical activity P\_HC1*

*I can't exercise, I have pain in my knees P\_HC2*

*I don't know where to go for physical activity P\_HC4*

### **General comments (20/82 responders)**

Identified themes from participants' general comments were: inclusion of dietary advice, project sustainability and a similar project was recommended for all including children e.g.:

*I suggest to add diet advice P\_HC2*

*Keep the project, don't stop P\_HC3*

*Develop similar projects for children P\_HC3*

*Develop similar projects for the public P\_HC1*

### **Responses from the POs**

Responses (12/16 respondents) to the open questions in the survey are listed in full as verbatim quotes in Appendix 11.5.

### **Topics which required more information**

Among those who responded to this question, half of them reported that they required more information on the PA behaviour change techniques (BCT) and PA measurement tools.

*We need more PA training especially on the behaviour change techniques PO1*

*More information is needed on the measurement tools or devices PO1*

### **Challenges to delivering the intervention**

Themes identified for challenges to delivering the intervention were categorised as physical challenges and logistical challenges including the following:

*No dedicated room/space PO3*

*Busy clinics PO2*

*Long questionnaires PO16*

*Managing appointments is difficult PO5*

*Handling accelerometers is difficult PO10*

### **General comments**

Themes to the general comments from the POs were related to sustaining the project and identifying available PA facilities in communities.

*WhatsApp Communications may be useful for future PA interventions  
PO8*

*Include PA in the Health information system PO3*

*Implement this project in all health centres PO12*

*We need information on the available PA facilities in the nearby  
community PO5*

### 9.3.2 Fidelity

The average scores from the observer evaluation audits on intervention delivery by the external assessor of 10% of the PA consultations were: 56/60 (93.3%) at baseline (n=12 consultations reviewed), 52/60 at 8 weeks (n=11 consultations reviewed) and 57/60 at 52 weeks follow up (n=9 consultations reviewed). All scores indicated high fidelity to the intervention delivery. Notably, no significant pattern was identified for the undone or incompletely/partially done items.

A general comment from the external assessor was

*“The fact that the consultation notes were organized to guide visit conversations led to a high level of adherence to the project protocol”.* External assessor

## 9.4 Discussion

This chapter aimed to provide evidence on the acceptability of the “MOVEdiabetes” study to participants in the IG and POs. Overall, the majority of the IG participants (who completed the 12 months study period) and all POs were satisfied with the “MOVEdiabetes” study. Out of 82, only two participant were quite dissatisfied and nine were neutral. Additionally, the majority of the participants perceived the programme as appropriate within primary diabetes

care in Oman. The fact that this intervention was delivered in a primary care setting may have enhanced intervention implementation and acceptance as this setting has been reported as being effective in PA promotion (Cobiac et al., 2009, Marcus et al., 2006, Eakin et al., 2004, Ashenden et al., 1997).

Additionally, primary health care is considered as one of seven best investments by the Global Advocacy for PA (GAPA & ISPAH, 2011, Bull and Milton, 2010). It is therefore reassuring for Omani researchers who may wish to upscale the current study or develop similar PA interventions within diabetes clinical settings.

Opportunities to ask questions and feedback was well received by both the participants and POs. In fact, the information received was perceived as more than necessary/far too much by more than half of the participants. A future assessment may be needed to explore which aspects of the project require more information on.

Worth mentioning, the communications in the “MOVEdiabetes” study were accessible and flexible throughout the study period. Participants had options for interactive communications with their peers and/or POs through WhatsApp or face to face contacts in the health centres within the scheduled visits to diabetes clinics. This may have initiated a positive social atmosphere for PA support (Lindsay Smith et al., 2017). This advantage may have contributed to their willingness to recommend the project to others and to their subjective perceptions to have had improved their PA behaviour. Findings from Chapter 8 confirmed the positive effects of psycho-social influences namely self-efficacy and social support on levels of PA (see Tables 8.2 and 8.3). However, future studies may consider exploring robust ways for effective and sustainable communications including providing information and feedback in promoting PA in diabetes care.

The intervention components/methods used in the “MOVEdiabetes” study were a practical translation of the recommendations from the formative work carried out to inform the PA intervention design (see Chapters 4 and 5). This study demonstrated that the “MOVEdiabetes” intervention components (face to face



personalised PA consultations, pedometer and WhatsApp use) within routine diabetes primary care were satisfactory, appropriate and acceptable by the majority of the participants and POs. However, some participants perceived the longevity as very poor or poor (device stopped working/recording the steps taken/day). Future interventions may consider devices with better quality and longer longevity.

Notably, highly rated intervention components by the participants were WhatsApp use followed by receiving PA consultations and then pedometer use. However, the POs gave more positive ratings for delivering the consultations, pedometers and then WhatsApp use. POs may value clinical based consultations settings as a normal part of their daily work and may not have time to engage in additional (outside the clinic) communications (Alghafri et al., 2017b, Verwey et al., 2016, Whitlock et al., 2002). However, this challenge was possibly diluted by the fact that the project was managed by a team of four members in each of the health centres who took turns to give feedback to participants. On the other hand, the participant/patients may have considered the WhatsApp communications as an additional flexible tool to discuss their health condition with their health care providers. This may have facilitated the establishment of a better patient-provider relationship reflected in the high participants' satisfaction on the opportunities to ask questions and getting answers/feedback reported earlier. The positive effects of using the WhatsApp phone application in promoting PA has been reported in few studies (Muntaner-Mas et al., 2017). However, given the lack of an association between the PA levels and scores from social support for PA reported in chapter 8 (see Section 8.3.2), more information is required on the long-term use of phone and text applications on promoting healthy behaviours.

Two themes for challenges of taking part in this project were identified by the participants and POs. Firstly, the multiple questionnaires (GPAQ, self-efficacy, social support, general well-being and exit questionnaires) used in this study were viewed as too long and time consuming. However these were used for research purposes and may not be used within the common routine diabetes

clinics. Future simpler versions of those questionnaires may be warranted. Secondly, delivery of the PA intervention was linked to pre-scheduled visits to diabetes clinics. Due to the dynamic and busy nature of the diabetes primary clinics as reported by the POs, future interventions may test the effectiveness of “stand alone” PA clinics that patients could be referred to vs the integrative “MOVEdiabetes” approach (Eakin et al., 2000). However, the fact that most participants found coming to the clinic for visits easy, may be attributed to the integrative approach adapted in the current study. Similar to many studies in nearby countries (Benjamin and Donnelly, 2013, Egan et al., 2013, Serour et al., 2007), hot weather was cited as a barrier by responders from the “MOVEdiabetes” study indicating the importance of discussing options for indoor PA and/or weather friendly timings for PA. However, addressing extreme weather conditions in promoting PA is under reported.

Finally, participants highlighted the need for advice on diet as an adjunct to PA and similar projects for all (the general population). These recommendations are of direct relevance to the National Health Policy Priorities in Oman, “5. To promote the health awareness of the community and establish a culture of healthy lifestyles” (Oman Health Vision 2050, 2012, Ministry of Health Oman, 2006 ). On the other hand, analysis of the qualitative data from POs stressed the need for more training on PA behaviour change techniques and measurement tools (Alghafri et al., 2017b). This may be essential for the continuation of the capacity building activities in PA across health care professions.

Challenges to delivering the intervention by the POs were no different from those reported in the literature e.g. the physical and logistical constraints (van Sluijs et al., 2004). Future extension of this project could look in to the best way to re-structure and organise the routine diabetes clinics to make them friendly to PA promotion to both patients and health care providers.

Notably, this work may be limited as the interviewer led approach may have discouraged the participant from giving negative comments (social desirability bias) (Grimm P, 2010). However, to ensure common understanding of the

questions this approach was viewed as appropriate. Participants were encouraged to give honest answers by stressing on the importance of their responses for future implementation strategies. However, more work may be needed to explore views and perceptions from anonymous approaches.

Moreover, despite piloting and revisions of the measurement scales described earlier (see Section 9.2.1), measurement bias cannot be excluded as a result of a possible unbalanced weighing/interpretive scale that may have skewed the responses from the participants towards positive responses. Future studies may consider a structured qualitative methodology (FGDs, or interviews) to explore programme implementation, monitoring and fidelity further. Importantly, insights from the external assessor indicated that the pragmatic personalised PA consultations provided a step by step guidance to adhering to the intervention delivery protocol. The “MOVEdiabetes” PA consultations guidelines could be used as a foundation for future well structured, and standard PA consultations within the health information system across the health care levels.

## **9.5 Conclusions**

The “MOVEdiabetes” study was perceived as satisfactory, appropriate and suitable. External assessment revealed that the intervention was delivered with a high fidelity. Overall, the suggested alterations to the PA intervention (inclusion of advice on diet, PA trainings, shorter PA evaluative tools, integration of PA in the HIS, and links to community resources) are hoped to lead to a sustainable PA service within the current primary health care setting that could be made available for the general population.

## **Chapter 10 : General discussion and conclusion**

### **10.1 Introduction**

This chapter provides a synthesized discussion of the formative work presented in chapters 4 & 5 and the findings from the main thesis project presented in chapters 6 to 9. Discussion within this chapter focuses on the limited research around an acceptable PA intervention method for use in routine diabetes primary care in Oman. The findings from the studies within this thesis were further considered to provide answers to the following questions:

- What are the implications of the results presented in this thesis on clinical outcomes and general wellbeing.
- What are the factors that are likely to influence PA levels (including socio-demographic factors and culture).
- What are the factors that are likely to influence primary health care providers to promote PA in diabetes primary care.
- What are the implications of the results presented in this thesis on the behavioural, psycho-social and ecological frameworks.
- How can the “MOVEdiabetes” study be up-scaled, disseminated and rolled-out

Methodological considerations, strengths and limitations of this thesis study are outlined, along with suggestions for future research direction and un-answered questions.

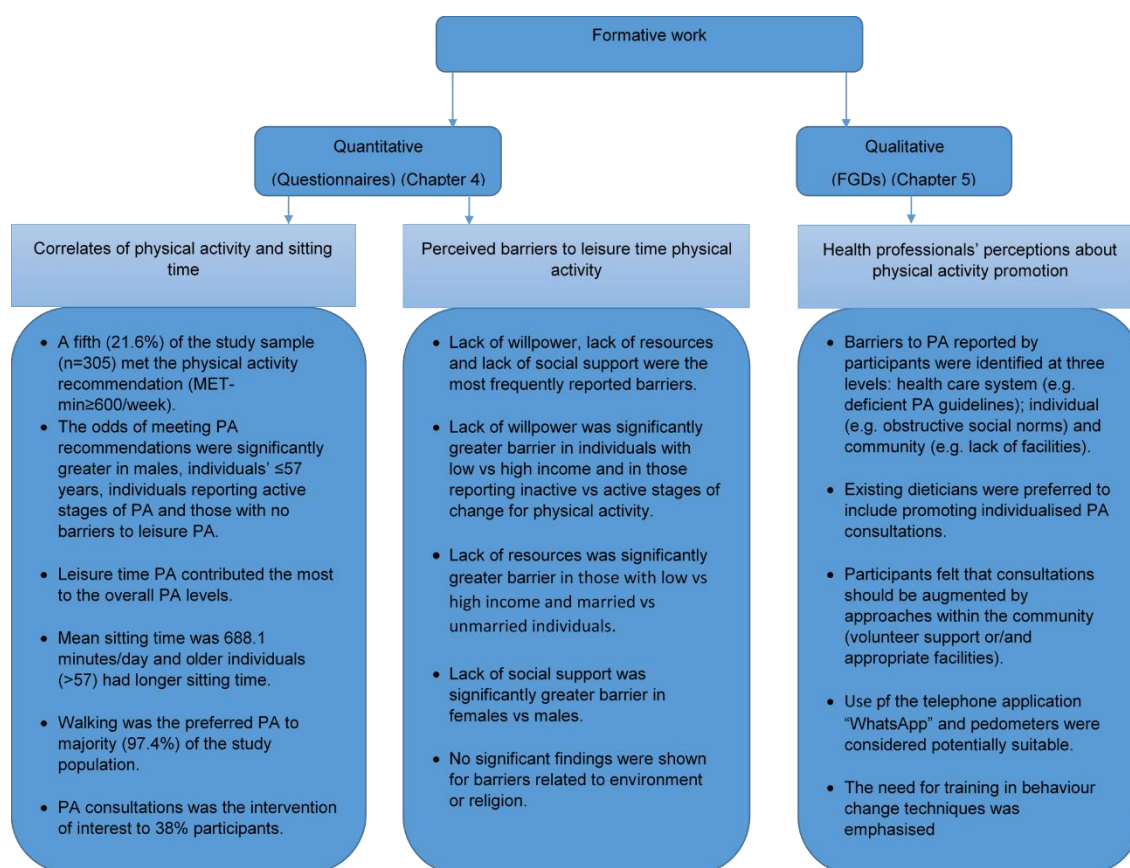
## 10.2 Key findings

The aim of the formative work was to collect preliminary quantitative and qualitative data on the physical activity levels, sitting time, barriers to performing PA and perceptions on appropriate PA methods in the current diabetes primary care setting. Findings from the formative work were used to inform a PA intervention design in diabetes primary care. The first study aimed to identify the prevalence and correlates of meeting 150 minutes of moderate to vigorous PA/week and sitting time in adults with T2D using the GPAQ questionnaire. Additionally, approaches to encourage PA in diabetes care were explored (see Chapter 4, Section **Error! Reference source not found.**) (Alghafri et al., 2017c). The second study examined barriers to performing leisure time PA, with data collected using the CDC questionnaire, and explored differences based on gender, age, marital status, employment, education, income and individuals' perceived stages of change in terms of PA (see Chapter 4, Section **Error! Reference source not found.**) (Alghafri et al., 2017a). The third study focused on exploring health care professionals' perception of barriers and opportunities, personal responsibilities and plausible PA promotional approaches within the routine diabetes primary care setting (see Chapter 6, Section 65.4) (Alghafri et al., 2017b). Key findings from the formative work (Figure 10.1) confirmed low levels of meeting the WHO recommended PA levels of 150 minutes/week of moderate to vigorous PA, and prolonged sitting time in adults with T2D. In the same population, the main barrier to performing PA was lack of will in both males and females. PA consultations were of interest to both: the adults with T2D and HPs. Walking was considered the most feasible PA to this population.

Overall, results from the literature search and formative work (Chapters 3 to 5) showed support for PA consultations, use of pedometers and the WhatsApp phone application as possible PA support to be integrated within the local current diabetes primary care. Summary results for each of these formative studies are presented in Figure 10.1. These methods constituted the intervention design in the "MOVEdiabetes" study delivered by trained project

officers to inactive individuals with T2D. The service was delivered within the diabetes clinics' normal working hours and every attempt was made to link the PA consultations with participants' original appointments.

**Figure 10.1: Summary findings from the formative work**



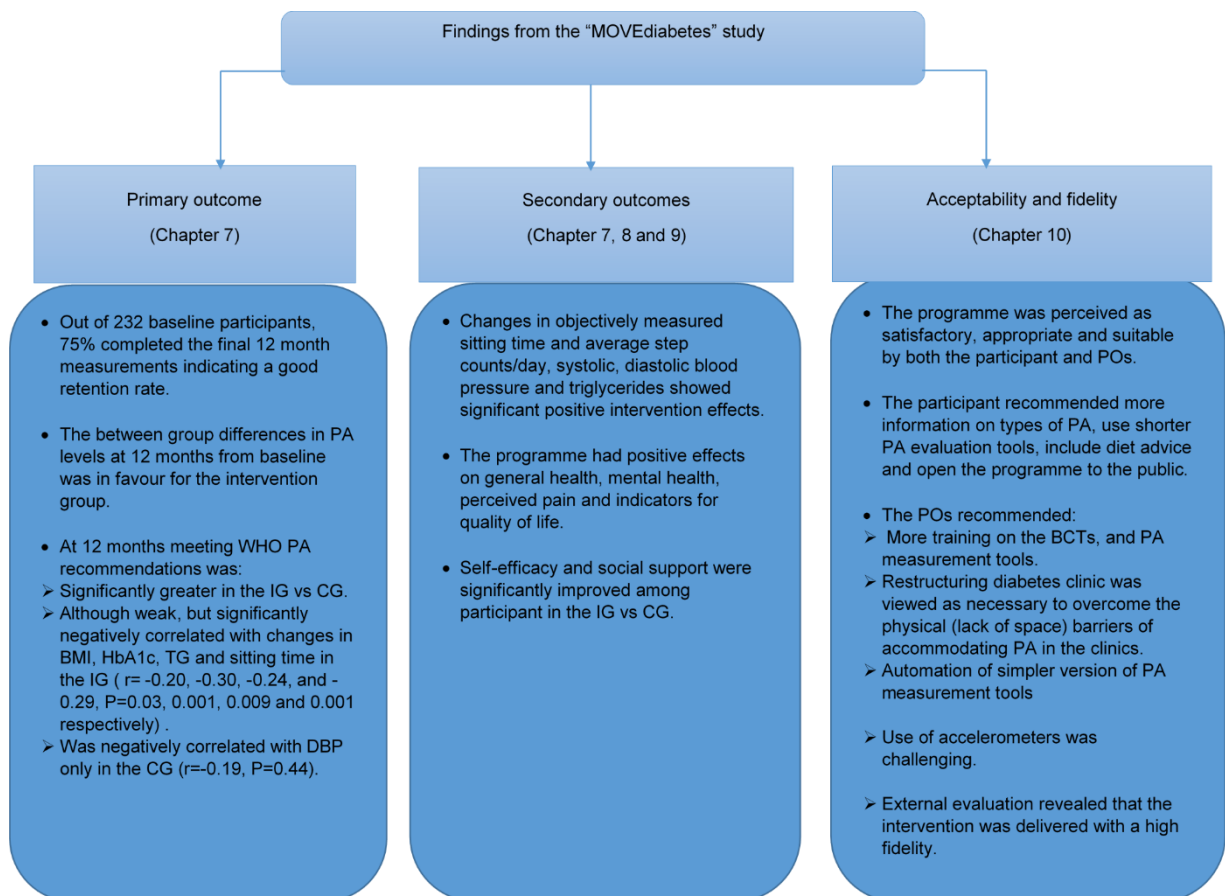
The primary outcome of the cluster randomised “MOVEdiabetes” study (see Chapter 7, Section 7.4) was ‘change in PA levels (MET.min/week) at 12 months’. Other secondary outcomes included objectively measured change in sitting time (hours/day) and step counts (steps/day) and anthropometric (weight and BMI), metabolic (HbA1c) and cardiovascular (blood pressure and lipids) outcomes. At 12 months, mean change in MET.min/week was significantly higher in the IG vs the CG. The between group difference in MET.min/week was in favour of the IG and odds of meeting PA recommendations were 1.9 times higher in the IG. Average steps /day measured objectively was +757 steps/day significantly higher in the IG vs CG. Reduction in sitting time (hours/day) was significantly more in the IG vs CG at both 3 months (-1.3, 95%CI -2.2 to -0.6) and at 12 months (-1.5, 95%CI -2.4 to -0.7).

Despite a lack of between group differences in changes in weight, BMI or HbA1c, there were significantly greater reductions in the IG compared to CG in blood pressure and triglyceride levels at 12 month follow up.

General wellbeing, and psycho-social changes were evaluated using adapted English to Arabic translated questionnaires (Alghafri et al., 2018). Findings from this part of the thesis illustrated the benefits of this intervention on general wellbeing across the studied health domains (sleep, pain, mental health, and quality of life). Changes at 12 months from baseline in both self-efficacy and social support for PA was in favour of participants in the IG vs CG.

Acceptability for the intervention (satisfaction, appropriateness and suitability) by the participants in the IG and all the POs to the study was evaluated using bespoke exit surveys. Results showed that the “MOVEdiabetes” study was acceptable including the PA methods used (PA consultations, pedometers and WhatsApp communications). The “MOVEdiabetes” intervention was delivered with high fidelity according to audits (20 item check list) undertaken by an external assessor (see Section 9.3.2). Summary findings of the “MOVEdiabetes” study are presented in Figure 10.2.





**Figure 10.2: Summary findings from the "MOVEdiabetes" study**

Overall, the majority of the participants across all the studies were overweight/obese (89% in the study sample of the formative work and 70% in the MOVEdiabetes participants) and with multiple comorbidities, >70% of participants diagnosed with hypertension and hyperlipidemia or both. Given the significant benefits of PA (see Chapter 3, Section 3.2.1), the high prevalence of these risk factors in this population support the importance of integrating PA within the diabetes routine care.

Notably, in adults with T2D, results from chapter 4 showed low levels of meeting PA recommendations (21.6%). This rate changed in participants IG vs CG of the "MOVEdiabetes" intervention from 10.7% vs 6.4% at baseline to 37.7% vs 25.5% at 3 months and 42.6% vs 28.2% at 12 months respectively. Differences in the rate presented in the formative work and baseline data from the "MOVEdiabetes" study is attributed to differences in population characteristics

as participants of the “MOVEdiabetes” study were screened to be physically inactive using the Scottish Physical Activity Screening Questionnaire (Scot-PASQ) (NHS Health Scotland, 2013).

In general, changes in PA level over 12 months confirm the positive impact of the “MOVEdiabetes” study on increasing the PA levels of adults with T2D.

Objectively measured sitting time at baseline, 3 and 12 months in participants (both the IG and CG) of the “MOVEdiabetes” study (mean sitting time of >13 hours/day) was higher than the self-reported sitting time in chapter 4, [see Section **Error! Reference source not found.** (mean sitting time of 11.5 hours/day). This findings indicate the importance of using objective PA measurement tools to address prolonged sitting time and sedentary behaviour in Omani adults with T2D.

### **10.3 Implications of the findings on clinical outcomes and general wellbeing**

In the current study, the PA intervention to promote increases in PA showed favourable clinically meaningful improvements in cardio-vascular outcomes namely reductions in systolic and diastolic blood pressure and triglycerides (Table 7.2). These findings confirm the consistent evidence on benefits of PA in diabetes care especially in lowering the risk of cardio-vascular diseases (Yates et al., 2014, Lee et al., 2014).

High blood pressure (responsible for 13% of deaths globally), high blood glucose and physical inactivity have been cited as leading global risks for mortality in the world (World Health Organization., 2015). In Oman, 73% of deaths are attributed to the Non-Communicable Diseases, of which 24.3% are due to cardiovascular diseases and hypertension, 7% due to cancer, and 2.2% due to diabetes (Oman Ministry of Health, 2016, Abd El-Aty et al., 2015). Hence, the fact that most of the participants (adults with T2D) across all studies in this thesis project were physically inactive and had hypertension, mandates a

shift in the management to prioritise PA behaviour change strategies in the management of NCD, including those with T2D. This is hoped to eventually reduce the burden of physical inactivity and NCD on population health and reflect positively on global economy (Ding et al., 2016).

It is notable that the risk of macro and micro vascular complications in T2D increases as BMI rises (Anderson et al., 2003). Obesity is also an independent risk factor for hypertension and hyperlipidemia (common comorbidities within the participants of the “MOVEdiabetes” study) as well as cardiovascular disease (Klein et al., 2004).

The null results for between group differences in changes in weight and BMI from the “MOVEdiabetes” study is justified as PA undertaken to improve blood glucose control and reduce CVD risk (e.g. 150 min/week of moderate to vigorous PA) is usually insufficient for major weight loss (Swift et al., 2014, Boule et al., 2001). Higher levels of PA (225-420 min/week) may be required to achieve significant weight reduction which may not be realistic to the population with diabetes in short term, low intensity interventions (Swift et al., 2014). However, successful interventions have demonstrated that in obese patients with T2D, PA and more extreme dietary energy restriction with very low-calorie diets can reduce HbA1c to <6.5% (48 mmol/mol) (diabetes remission) and fasting glucose to <126 mg/dL (7.0 mmol/L) in the absence of pharmacological therapy or surgical procedures (Lean et al., 2018, 2017). Due to the fact that all the participants received dietary advice as part of their routine diabetes care, the “MOVEdiabetes” intervention did not focus on diet, just PA and thus individuals’ attention to their diets may not have been as good. This significant addition was recommended at the end of “MOVEdiabetes” study (exit survey) by the participants in the IG (see Chapter 9, Section 9.3). The best evidence for the effectiveness of intensive lifestyle modification (diet and PA) on the management of diabetes has been provided by the Look AHEAD project (see Chapter 3, Section 3.5.2, Table 3.3). Despite the lack of effect of the intensive lifestyle intervention program on risk of cardiovascular morbidity and mortality, significant positive effects on weight, waist circumference, physical fitness and

HbA1C were noted in patients with T2D in the intervention group (Johnston et al., 2014, Wadden et al., 2012, Unick et al., 2011). In addition, participants who received the intensive lifestyle intervention were significantly more likely to experience remission of diabetes compared to the comparison group who received usual diabetes support and education (Gregg et al., 2012). Future PA behaviour change interventions may consider the addition of dietary advice.

In the current study, positive changes in PA resulted in a reduction in median HbA1c levels within the “MOVEdiabetes” at 12 months from baseline in the IG only (-0.4%,  $P=0.03$ ). However, this reduction in HbA1c may not be attributed to changes in PA levels only as other factors such as changes in diet were not included in this study. Evidence across studies has shown that PA reduces HbA1c by 0.66% in adults with T2D, a percentage that should substantially reduce the complications of T2D (Najafipour et al., 2017, Colberg et al., 2010b, American Diabetes Association, 2010). However, the lack of between study group differences in change in HbA1c could be attributed to the possible adjustments in the hypoglycemic treatment plans that were not controlled for within this study. For example, it is possible that drug doses may have been changed including insulin doses to participants in the control group which may have diluted the intervention effect. Additionally, potential Hawthorne effect cannot be excluded as participants in the CG may have been more diligent in their glycaemic control knowing that their HbA1c, and weight was going to be assessed again at follow up.

The interest in PA to improve mental well-being is a growing research area (Biddle, 2016), however, this was not within the scope of the current research project. The “MOVEdiabetes” study provided fundamental evidence on the effectiveness of PA in improving the general wellbeing, feeling calm/peaceful, energetic and less depressed in both the study groups. Restrictions in daily activities due to emotional health were reduced with the increase in PA levels in the IG only. Given the fact that adults with T2D may potentially have more mental/psychological disturbances compared to the general population namely depression (Gillison et al., 2009), evidence from the “MOVEdiabetes” study

could inform further work to consider recognizing a holistic intervention strategy for DM patients including assessments for mental health as an integral part in diabetes management (Young-Hyman et al., 2016, Ducat et al., 2014). In the Arab world including Oman, however, validated mental health screening and assessment tools are required.

Pain was one of the reasons given for individuals dropping out from both of the study groups (Figure 7.2), however pain was significantly reduced with the increase in PA levels in the IG. This finding has to be interpreted with caution as the type of pain was not investigated in this study. Pain could be a danger sign in adults with T2D that requires further investigation and management. However, chronic pain (myalgia) has been estimated to affect 60% of adults with diabetes and is strongly associated with reduced activity tolerance (Krein et al., 2005). These findings emphasize the importance of considering chronic pain when exploring interventions targeted at increasing PA for patients with T2D (Riva et al., 2013).

Member states of WHO have recently agreed to a 10% relative reduction in the prevalence of insufficient PA by 2025, as one of the nine global targets to improve the prevention and treatment of non-communicable diseases (World Health Organization, 2018b). The “MOVEdiabetes” intervention provides an opportunity to increase PA levels for individuals with T2D and has elicited some meaningful clinical positive changes in cardio-vascular outcomes, mental wellbeing and perceived pain. However, PA alone is unlikely to be enough to address the overweight/obesity problems of this study population (discussed later). Management of diabetes may consider integrating wider approaches to promote general wellbeing and diabetes control through behaviour changes in other aspects of diet and lifestyle as well as PA.

## 10.4 Factors that are likely to influence PA levels including (socio-demographic factors and culture).

### 10.4.1 Socio-demographic factors (gender, age, education, employment and income)

Globally, females are less likely than males to be achieving PA recommendations in both the general population and adults with T2D (Guthold et al., 2018, Hamasaki, 2016). This difference is wider in the Arab world (Sharara et al., 2018, Mielke et al., 2018). Physical inactivity (<3.0 METs) among the female population in the GCC region is reaching an alarming level, ranging from 50.7 to 98.7% (Alshaikh et al., 2017). Results from the formative work (see Section **Error! Reference source not found.**) confirms the gender differences in activity levels in favour of males (34.6% males met the WHO PA recommendations vs 12.0% females) (Alghafri et al., 2017c). Females did less PA (work, travel and leisure) and what they did was of a lower-intensity activity than males (see Section **Error! Reference source not found.**). The main perceived barriers to performing leisure time PA in females with T2D in the current study were lack of willpower and social support (see Chapter 5) (Alghafri et al., 2017a). Similar barriers were reported in studies by Mabry et al. (2016), Abbasi (2014) and Mabry et al. (2010b) but also childcare, household work, cultural beliefs (e.g. appropriate PA clothing), social isolation, living in extended families, unsafe neighbourhood environment, and absence of culturally appropriate facilities. Offering more opportunities for safe (e.g. closed indoor gym facilities), accessible leisure-time activity and options for social support to females in the Arab world including Oman in order to increase their overall levels of activity may therefore help close the gender gap.

To address the reported barrier on lack of social support particularly from females (see Chapter 4, Section **Error! Reference source not found.**), participants in the “MOVEdiabetes” study were asked to attend their PA consultations with a friend, spouse or any member of his/her family that could

provide social support for PA (e.g. a person that could walk with the participant 'buddy' or provide encouragement). Additionally, to adhere with the cultural norms, the WhatsApp group compositions/communications were gender specific and females had the opportunity to discuss their PA performance with the other peer females in the group. It was hoped that this would provide social support to the participants to perform more PA.

Although not reported in the current study, it is recognized that within the GCC, which includes Oman, the excessive hiring of domestic workers/ housemaids and use of cars are potential barriers to PA and are likely to be contributing to the low activity and sedentary lifestyles seen in the current studies (Benjamin and Donnelly, 2013, Mabry et al., 2010a). Other studies report that for many GCC adults, particularly women, common lifestyles include frequent social gatherings, excessive food consumption and sedentariness which are all barriers that require further exploration in the GCC countries (Serour et al., 2007). Studies may be required to evaluate the impact of such gatherings on health and the challenges that may be associated with making positive changes to these cultural aspects of lifestyle.

Female participants included in the various studies within this thesis had a higher BMI (more obese) than males (within the "MOVEdiabetes" study, mean BMI in females was 34.5 (8.8) kg/m<sup>2</sup> vs 31.9 (7.1) in males). Recent estimates of overweight/obesity are in the order of 59% in Omani females (aged 15-49) (Ministry of Health Oman, 2016b). In addition to availability of high energy-density diets and physical inactivity, multiple pregnancies (although not studied in this thesis) may contribute to this weight gain, as the fertility rate (live births per women 15-49 years) is four which is higher than the global rate of 2.4 (Max Roser, 2018). Multiparity was also found to have negative association with both T2D and PA, and on the next generations' risk for diabetes (Garawi et al., 2015). Thus health policies in Oman may consider opportunities to prevent and control excess weight gain in the general population and particularly for females.

Moreover, compared to males, females who took part in the studies included within this thesis, had lower levels of education. Illiteracy has been shown in other studies to be associated with both physical inactivity (Sharara et al., 2018) and higher risk for T2D (Al-Moosa et al., 2006). Within the “MOVEdiabetes” IG, a significantly greater increase of +500 MET.min/week ( $P=0.04$ , 95%CI 33.0 to 1144.4) was shown in individuals with high (> secondary education) vs low education ( $\leq$ secondary education). Low levels of education may be linked to lower knowledge and understanding of the importance of recommended types and amounts of PA and thus a lower likelihood of engagement in PA. Hence, options for PA education including benefits of PA should be prioritised within the health educational programs in primary diabetes care.

Individuals’ older age has been reported as an un-avoidable risk factor to not achieving WHO PA recommendations in those with T2D (Brazeau et al., 2015b, Heiss and Petosa, 2014). Meeting the PA recommendations was significantly associated with younger vs older age in both the “MOVEdiabetes” study groups (in the IG OR= 1.1 vs 1.5 in the CG). Also, results from the formative study presented in chapter 4 showed that older individuals (>57 years) had significantly longer sitting time compared to individuals  $\leq 57$  years (OR 2.8, 95% CI 1.7 to 4.6). Hence, promoting PA in diabetes care should include ways to meet individual age related expectations namely physical status, and personal PA preferences especially that more than one fifth of the participants in the “MOVEdiabetes” study (see Section 77.4.2) and more than half of the participants in the formative study (see Section **Error! Reference source not found.**) were aged >50 years.

Despite the fact that more males than females were employed across all sub studies employment was not associated with meeting the PA recommendations (Alghafri et al., 2017a). A focus on the work PA domains may be considered in future studies especially that given that more than half of the participants in both the “MOVEdiabetes” study groups were employed. This could include interventions to increase PA and reduce sitting time at work places via walk and talk meetings, marked worksite walking paths, standing desks and interrupted



screen time programmes (Chau et al., 2010). However, a cross-sectoral (governmental and non-governmental) approach may be required to achieve the goal of active work places in Oman (Reis et al., 2016).

Higher income (see Chapter 7, Section 7.4.3 ) was associated with a greater increase in PA levels within the intervention group in the current study (Alghafri et al., 2018). This finding may be linked to greater awareness of health issues and greater purchasing capacity for resources such as, pedometers, watches with PA monitors, treadmills or gym memberships (Bauman et al., 2012b) that could facilitate positive PA behaviour change in individuals with high income (Kari et al., 2015). Therefore, low cost options for PA namely walking, a preferred PA (see Chapter 4 and 6), should be prioritised to all individuals especially those with low income.

#### 10.4.2 Culture

Objectively measured sitting time was significantly higher in the current study population compared to the general population in nearby countries (>12 hours/day) (Alghafri et al., 2018, Alghafri et al., 2017c). In Saudi Arabia and Kuwait reported sitting times were >4.5 hours/day (Ministry of Health Saudi Arabia, 2005) and >3.7 hours/day (Ministry of Health Kuwait, 2006) respectively. These differences may be attributed to differences in population characteristics and measurement tools. However, sedentary behaviour and sitting time has been associated with T2D (Ekelund et al., 2016, Hamasaki, 2016). Culturally, sitting behaviour of this population in the Arab world is under reported (Mabry et al., 2013) and requires further exploration and opportunities to shorten/interrupt sitting time e.g. sitting time while cooking and house work, social gatherings, and meditation/prayer.

Although hypothesized and reported elsewhere (Donnelly et al., 2012), religion was not reported as a significant barrier for leisure time PA in the current study. Beliefs on PA dress codes and gender mixed PA facilities may require exploration to whether they are accepted religiously. There could be a positive

bias in reporting views on religion as people may not wish to say anything negative about faith. However, generally, some comparative analyses across countries reported that Muslim countries were more likely to be physically inactive, and seemed to suggest that religion may be an obstacle to PA (Kahan, 2015). This however is not consistent with the religious principles in the region (Benjamin and Donnelly, 2013). There is no evidence linking religious beliefs to low PA. In Syria, a study compared PA between Muslims and non-Muslims individuals. Results found no significant differences in PA between Muslim and non-Muslim Syrians (Lucero et al., 2014). Such research highlights the complex interaction between multiple factors at multiple levels (individual, environmental and societal) that may hinder PA (see Section 3.5.5). However, opportunities for positive religious beliefs such as “being physically active brings blessings to the individual”, should be explored and used to encourage positive PA behaviour especially in females (Attarzadeh Hosseini and Hejazi, 2016, Abbasi, 2014).

The current project started and ended in the month of Ramadhan and thus both baseline and 12 months follow measures were collected during Ramadhan. In Ramadhan, Muslims abstain from drinking and eating from sun rise to sun set 10 to 19 hours every day for ~30 days. (Donnelly et al., 2012). Working hours are reduced in many Muslim countries and dietary habits during Ramadan differs from the rest of the year including the amount of consumed fat, protein and carbohydrate (Attarzadeh Hosseini and Hejazi, 2016, Guma et al., 1978). The effect of Ramadhan in the “MOVEdiabetes” study was not explored. Thus it is not possible to link any of the study findings to fasting in Ramadhan especially due to the fact that both the study groups were subject to Ramadhan. However, a study in Qatar showed positive effect of Ramadhan fasting on reducing lipids, and improving HbA1c in the short time (Bener and Yousafzai, 2014), nevertheless similar evidence on PA levels was inconclusive (Attarzadeh Hosseini and Hejazi, 2016). In Iran, favourable alterations were reported when fasting was combined with regular PA specifically in lipid profile, haemoglobin and blood glucose levels (Attarzadeh Hosseini and Hejazi, 2013). Hence, despite feeling less energetic during hours of fast, Ramadhan can possibly be a

potential opportunity for prompt improvements in PA levels but may not be enough for sustained behaviour change.

### **10.5 Factors that are likely to influence primary health care providers promotion of PA in diabetes primary care.**

The range of different health care professionals who were included in the exploratory study (n=29) expressed a common need for support for PA promotional activities in diabetes care (see Chapter 5, Section 5.4.3). Specific measures that could be usefully considered are provision of updated and well communicated PA guidelines from a recognized professional association e.g. The Oman Diabetes Association. Implementation of these guidelines in practice could ideally be supported by the establishment of a well-resourced unit for promoting PA in diabetes care including appropriate equipment (e.g. pedometers) and practical advice on how professionals can help patients utilize self-monitoring and other BCTs. This is supported by the recent launch of the national action plan for Non Communicable Diseases including PA in February 2018 (Oman Ministry of Health, 2018). The provision of funded, accredited (pre-service and/or in-service) PA training of health staff would help to ensure the development of standards of practice across the sector as well as provide a clear signal that this area is an important aspect of care.

The current diverse multi-disciplinary team (physicians, nurses, health educators, pharmacists, and dietitians) involved in diabetes care management in primary care widens the options for delivering PA activities to patients with T2D. Strong multi-disciplinary medical teams within staff become an essential part of PA intervention to ensure the reinforcement of the PA messages to patients. However in the “MOVEdiabetes” study, dietitians were considered more appropriate to deliver, monitor and follow up PA services in primary settings. Others PA approaches utilising non-dietitians could equally be evaluated in future work such as clinical pharmacists (Abdulkarem and Sackville, 2009) or PA trained psychologists (Matthews et al., 2017)

In order to deliver an effective intervention, PA needs to be re-conceptualised as medicine within the diabetes care management team (see Section 55.4.3) (Dacey et al., 2014).

Regular and structured academically accredited PA training programmes (packages) are required for all health care providers. Suggested topics include PA definitions, measurements, endorsement, consultations, interventions, and use of behaviour change techniques (Dacey et al., 2014). PA training for all health care providers is an essential part of PA intervention programmes to ensure continuity of delivering PA services within health care setting where the staff turnover rate is high and staff transfers are frequent.

### **10.6 The implications of the study findings with regards to behavioural, psycho-social and ecological frameworks**

Effective behaviour change interventions for promoting PA in adults with T2D are often grounded in a theoretical framework (Avery et al., 2016, Avery et al., 2015a). The BCTs that were used in the delivery of the “MOVEdiabetes” PA consultations (see Table 3.5.7) were drawn from perceptions from the local population and their HPs and also from the constructs of the theoretical models (the trans-theoretical model, health belief model and the social cognitive theory) (see Chapter 3, Section 3.5.5) (Alghafri et al., 2017d). Notably, using local data to inform a culturally congruent PA intervention design, the “MOVEdiabetes” study may have facilitated the transfer of evidence from the west to meet the local Omani clinical and cultural expectations.

A number of findings from the exploratory/formative studies highlight some key issues that needed to be built into the design. For example, lack of will power for PA was rated highly as a barrier to performing PA by both males and females (Alghafri et al., 2017a), it was therefore important to find ways to enhance self-efficacy, motivation and determination for PA for example, by linking the PA consultation to BCTs such as setting modest and achievable goals (Lindsay Smith et al., 2017, van der Heijden et al., 2014). Other BCTs

applied in the “MOVEdiabetes” intervention included action planning, self-monitoring of behaviour, barrier identification, use of follow up prompts and social support (see Figure 7.1) (Cradock et al., 2017). Notably, options for social support (especially for females) were integrated within the consultations and WhatsApp communications between the participant and their POs/peers.

The PA consultations also included discussing the type of PA, when, where and how much to perform (Alghafri et al., 2018) which were recently recommended by (Yanai et al., 2018, Kwasnicka et al., 2016). These elements encouraged practicing exercise prescription by the POs to meet the individual needs of the participants of the “MOVEdiabetes” study specifically the older individuals and with those with multiple comorbidities.

It is evident that planning a service for improving patients PA levels in a diabetes primary care setting would require a multi-level and cross-sectoral approach to fully optimise positive PA behaviours (Figure 10.3). Based on findings from the literature search (see Chapter 3) and across studies of this thesis, at the individual level, PA consultations should aim to: a) Provide information on the benefits, b) Support individuals to make specific, measurable, achievable, relevant, and timely (SMART) PA short and long-term goals, c) Discuss barriers to PA and ways to overcome them, d) Provide ideas on places and times to access local PA opportunities, e) Use follow-up prompts including telephone and face-to-face sessions and/or other technological tools, f) Provide ideas for making time to be active across all domains (work, travel and leisure), g) Encourage individuals to gain social support from others (family/friends) to help achieve PA related goals, and h) Congruence of the new behaviour with the patients’ beliefs and values namely the positive religious thoughts on performing PA and appropriate clothing for PA (particularly in females).

Findings from the qualitative exploratory formative work showed that current health care providers are interested to include PA within diabetes management (see Chapter 5, Section 5.4.3), however a multilevel (local, regional, and central) and cross-sectoral approach (governmental and non-governmental

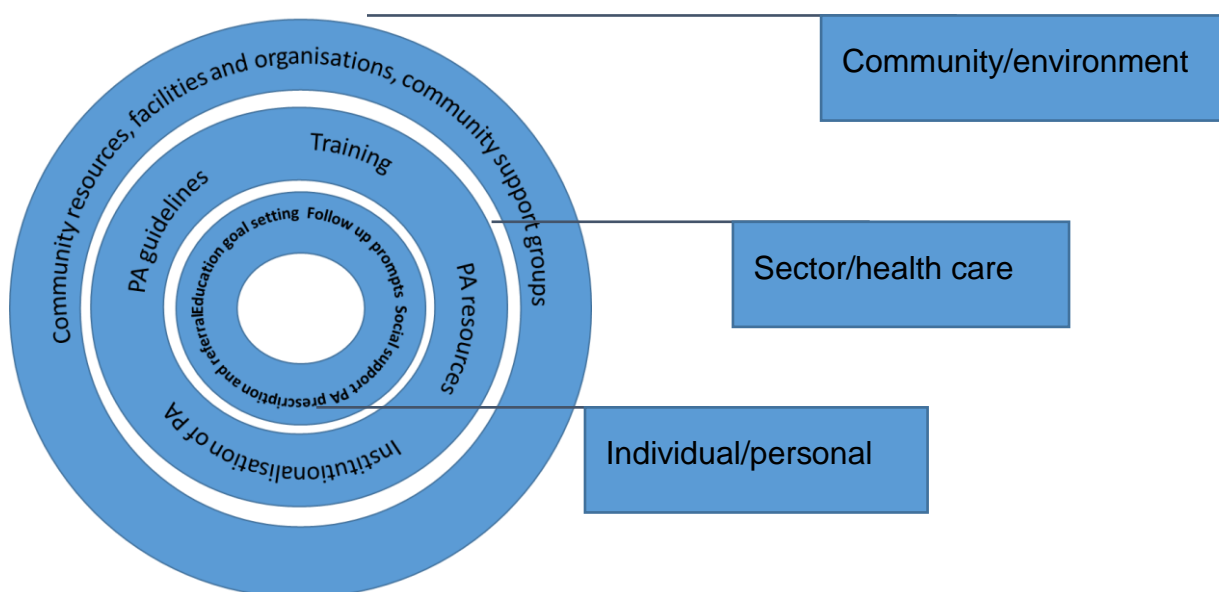
organisations) is needed to address the current barriers to delivering PA services within the clinical setting (Reis et al., 2016).

At sectoral (health care) level, PA interventions may require legislation and policy to enforce PA support in diabetes care, education and training for health care providers, and monitoring/evaluative tools to help sustain the implementation of PA services within clinical settings. Health care providers in the exploratory study presented in Chapter 5 (see Section 5.4) and POs perceptions presented in chapter 9 (see Section 9.3) highlighted the need for the Oman Ministry of Health to have well communicated PA guidelines and PA training for HPs. Ultimately, overall success of a sustainable PA integration within diabetes primary care could be evaluated within the national annual progress reports (Ministry of Health Oman, 2016a).

Walking seemed to be socially acceptable in this study population (see Section **Error! Reference source not found.**) (Koorts et al., 2018, Reis et al., 2016, Ogilvie et al., 2007). In addition to its no/low cost, walking has been associated with decrease risk of weight gain which is a major risk factor for T2D, other cardiovascular diseases and cancer (World Cancer Research Fund International, 2018). However given the fact that it may not be feasible to walk in extreme hot weather conditions, opportunities for indoor safe, feasible and affordable PA facilities are warranted. Hence, at the environmental and community level [similar to recommendations in the literature (World Health Organization, 2018a)], these initiatives may need to be gender specific to address cultural expectations. However, information on successful interventions to overcome the environmental barriers in Oman and nearby countries is limited. Future research may be directed to evaluate the effectiveness of indoor PA options in increasing PA levels in adults with T2D.

Effective governmental policies can include the provision of cycling and walking infrastructure, improving road safety, and creating more opportunities for PA in public open spaces and parks, in workplaces, and in other local community settings (Reis et al., 2016). However, evidence on the effectiveness of such interventions is yet to be explored in the Arab world. Additionally, planning for

effective PA interventions requires identifying supporters and allies to PA promotion for adults with T2D (Reis et al., 2016). This would ideally include provision of options to increase choices for PA facilities (Gym, open spaces) or peer active groups (walking supporters) within the community that patients could be referred to or access themselves.



**Figure 10.3: Levels of PA functions suggested to support the PA behaviour change in adults with T2D**

### **10.7 Implications of study findings on programme implementation, upscaling, dissemination and roll-out**

The “MOVEdiabetes” study provided practical evidence on the effectiveness of personalised face to face consultations, and use of WhatsApp and pedometers in increasing PA levels in adults with T2D. The approach of utilising the existing staff (three trained POs/health centre) to conduct the intervention over the 12 months is well supported in the literature of translational research (Koorts et al., 2018). Notably, the dietitians were selected by HPs to be the most appropriate personnel to conduct the PA consultations (see Section 5.4.2), However,

participants of the formative work presented in chapter 4 (see Section **Error! Reference source not found.**) gave a range of options for who should be responsible to deliver PA services in diabetes primary care. Overall, it is believed that having multidisciplinary teams recruited as POs (doctors/nurses/dietitians/health educators) (see Section 6.3.3) within the selected “MOVEdiabetes” health centres have overcome the potential threat of service interruptions/discontinuation related to frequent staff turnovers in primary care in Oman. For example, while dietitians were delivering the PA consultations, other POs were collecting the other “MOVEdiabetes” secondary data namely questionnaires on general wellbeing, self-efficacy, social support and facilitating the WhatsApp communications. However, assessment bias, work overload and staff attitudes are areas that require future investigation.

Furthermore, the utilization of existing resources to deliver the intervention over the 12 months could be viewed as cost saver yet to be confirmed in future studies. The improvements in general health and reduction in perceived pain reported in chapter 9 as a result of the intervention may be a reflection of additional cost benefits. However, the cost of inactivity on poor health and days lost from work is overwhelming; investigating PA behaviour changes at population level could reflect significantly on the economical savings at country level (Ding et al., 2016).

Moreover, subject burden was recognised as a barrier to all subjects completing the study. Despite efforts by the investigating team to minimise this in the preparatory stages of the MOVEdiabetes intervention by critically discussing minimum data set requirements, both participants and POs reported that questionnaires were long and suggested shorter versions in future studies. However, the “MOVEdiabetes” study measurement tools were not part of the actual intervention and thus would not be part of a wider roll out of the study. Developing shorter PA measurement tools should facilitate integration of PA in the current health information operating system and dissemination across other clinics.



Upscaling is defined as extending the reach of an intervention by replicating it in other localities, or cities (horizontal scale-up) (World Health Organization, 2009b) or institutionalising the intervention at government level so it could reach all citizens within a given area (vertical scale-up) (de Silva-Sanigorski et al., 2010) or ideally, a combination of the two (horizontal and vertical) (Reis et al., 2016). The current findings could be scaled up to provide a platform for possible routine diabetes screening services to promote PA for all individuals visiting primary care in Oman. However, this may require adaptation of simpler PA assessment tools as well as behaviour change counselling techniques.

Despite program acceptability by participants of the “MOVEdiabetes” programme and the POs (see Table 9.1 and Table 9.2) further structural, educational and technical adjustments are required to strengthen the integration and upscaling of PA services within local settings (Koorts et al., 2018). Dissemination of findings from this project has begun through partnerships with various managerial and a non-health academic organisations (the Sultan Qaboos University, The Research Council (TRC) and Endocrine Centre) to promote sustainability of the project. Early region-specific roll-out of the “MOVEdiabetes” intervention components into routine diabetes care is hoped to facilitate ongoing practice to promote PA. Further, publishing the different studies that make up this thesis in peer reviewed literature as well as presentations at international and national conferences facilitates national and international dissemination (see Appendix 1.4, 2.4, 1.5, 1.6 and 1.7).

## **10.8 Methodological consideration**

Although formative studies undertaken were used to inform the main intervention study, in conjunction with use of recognized BCTs, there are aspects regarding the design and certain methods that have been used that are worthy of discussion.

The self-monitoring and reporting/feedback strategies used in the “MOVEdiabetes” study via pedometers and WhatsApp communications allowed

the participants in the IG (group WhatsApp application) to compare their own step count pattern posted over the week and compare their performance with that of other peers in the group. This was hoped to motivate participants to perform more PA through enjoyable group dynamics (Kwasnicka et al., 2016). Notably, findings from chapter 10 showed significant between group differences between baseline and 12 months follow up in social support from friends, but not from family. This may have been supported by the fact that participants in both the individual and group WhatsApp application reported/discussed their step counts to their POs in their respected health centre or peers, respectively. Additionally, findings from chapter 11 showed high ratings on acceptability of both the participants and their POs on these intervention components.

Within the budget constraints accelerometers (activePAL™) were possible for only a subset of population. After using it, both the participant and POs reported being un-comfortable with using the accelerometers. It was cited as the main reason of drop out by participants in the intervention and comparison groups (see Chapter 7, Section **Error! Reference source not found.**). The main problems were associated with skin irritations due to the adhesives around the devices and dispositioning of the devices. Future intervention designs may consider alternative devices and/ or wear protocols to improve compliance.

Conflicts and debates about which monitor(s) to use (ActivePAL vs ActiGraph), where to position them on the body, and how to process the data are still common in the field of PA research (Troiano et al., 2014, Trost and O'Neil, 2014). Summary of PA outputs extracted from questionnaires and accelerometers has been repeatedly demonstrated to have a low to moderate correlation (Dyrstad et al., 2014), but these distinct assessment methods are not equivalent nor interchangeable. Accelerometers quantify acceleration resulting from PA-associated body motion/movement at a fixed point of the body (i.e. in this study it's the hip) (Chen et al., 2012). In contrast, self-report instruments attempt to quantify PA based on reported time periods engaged in specific behaviours of longer duration (see Chapter 3). The subjective nature of PA questionnaires can result in bias and inaccurate over reporting of results.

However, the use of subjective vs objective PA measurement tools usually depends on research questions, desired outcomes, and availability of a budget for the required population size (Chan et al., 2017).

Moreover, data obtained from the accelerometers in the “MOVEdiabetes” study outputs was complex and with multiple invalid number of days (see Section 7.3.4). This did not allow for comparisons with results on PA levels from the questionnaires (Alghafri et al., 2018). Objective-based devices will increasingly be used in PA research, however this will require ways to improve adherence to accelerometer wear protocol and analysis guidelines (see Chapter 3, Section 3.3).

The cluster randomised controlled design was selected in the “MOVEdiabetes” study to minimize between group contamination by having the two groups (intervention and comparison) from independent health centres. The unit of inference in this approach allows for analysis at cluster and not individual levels (Donnar and Klar, 2004, Donner and Klar, 2000). Notably, the interpretations at individual level analysis is typically directed for efficacy of an intervention, while studies in primary care settings are usually directed at the cluster level to give, in addition to efficacy, meaningful reflections on improvements in the implementation of an intervention (Foy et al., 2001). Therefore, the cluster randomised design seemed to be appropriate for the “MOVEdiabetes” study which looked at both efficacy and implementation outcomes.

Given the limited time frame and resources for this study, the sample size for the “MOVEdiabetes” intervention was primarily based on between group differences in PA levels. Future studies may consider a larger gender segregated sample size to elicit the gender effect on PA levels presented in chapter 4 and cited globally.

Missing data is a potential bias to RCTs and was dealt with care using an intention to treat analysis according to the last value carried forward imputation for missing data at 3 and/or 12 months and a mean imputation procedure where baseline data was missing. Mean change in PA levels (MET.min/week)

obtained from participants who completed the 12 months period (without the missing values) was higher than the mean PA levels obtained after the imputation procedures in the IG [+806 (n=82) vs +631 (n=122) respectively]. Also, the between group difference was higher for the sample who completed the 12 months follow up (n=174) compared to the sample after the multiple imputation procedure (n=232 +665 vs +447 respectively). This indicates that the imputation procedures appears to have diluted the intervention effect and despite the reasonable retention rate of the “MOVEdiabetes” study (75%), future studies may attempt to minimise drop-out rates through frequent monitoring of participants’ attendance to the clinics. Also, participants’ drop-out rate may be improved by managing concerns such as offering hypoallergenic adhesives to the individuals with skin irritations from use of accelerometers adhesives.

## **10.9 Strengths and limitations**

### **10.9.1 Strengths**

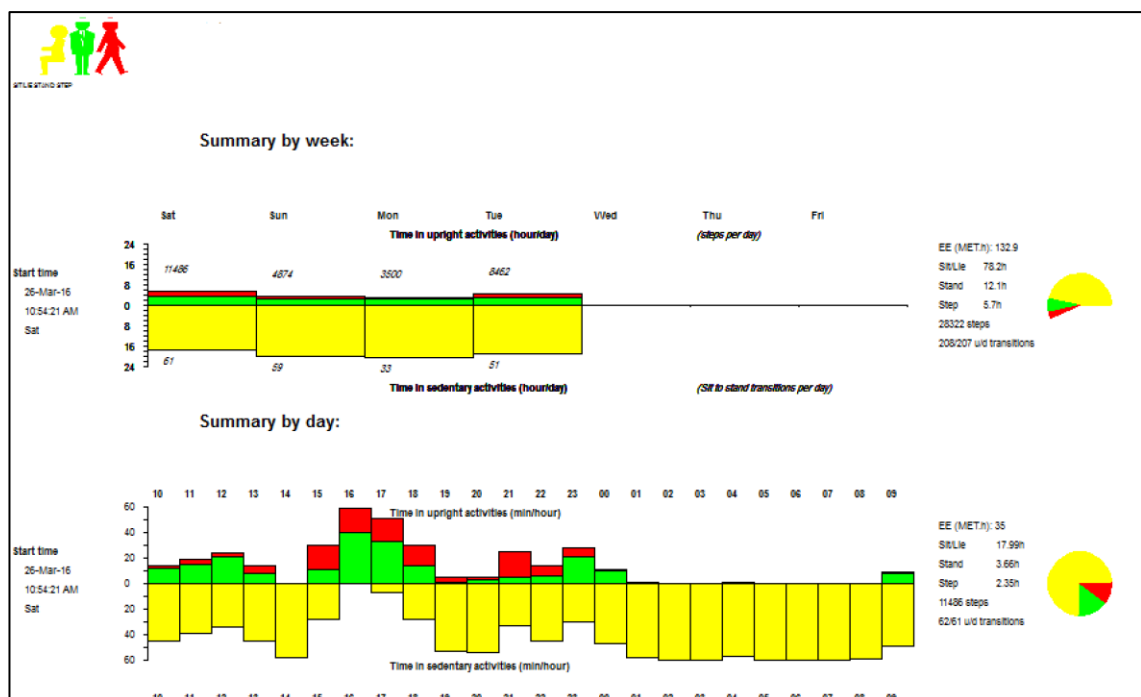
Responding to the limited longitudinal PA intervention designs in diabetes care, this project may be considered as an example of PA promotion in diabetes primary care that could be replicated elsewhere (Hamasaki, 2016).

This is the first study in Oman exploring the implementation/integration of PA consultations within routine diabetes primary care. Results indicate the possibility for implementation, upscaling and roll out of the intervention to other regions in Oman or perhaps to other neighbouring countries with similar socio-demographic, cultural and health care systems.

Despite its complexity, the use of accelerometers provides expertise in Oman to follow recent trends in conducting PA interventions using objective PA tools (Troost and O'Neil, 2014). Although concerns were raised earlier regarding the data generated from the accelerometers to estimate overall PA levels, they could be used to study the sedentary behaviour (a globally growing research

area) (Ekelund et al., 2016). The sedentary behaviour in the Omani population is less understood, but appears to be high (see Chapter 4, Section **Error! Reference source not found.** and Chapter 7, Section 7.4.4 ), which is of concern. However, the cost of using objective PA measurement tools is considered a challenge (Corder et al., 2007).

Importantly, summary outputs from using the accelerometers for seven days prior to the appointed PA consultations were discussed with the participant (Image 10.1). The graphical presentation (yellow is sitting, green is standing and red is active) were used as an educational tool which may have helped to motivate participants to make changes and see progress. These images were simple and delivered a powerful messages to set goals towards increasing PA. However, more work may be needed to replicate these graphical outputs within the routine services without using relying on expensive accelerometers.



**Image 10.1: Image from activePAL accelerometer outputs**

Due to limited PA research in the Arab world, the “MOVEdiabetes” study may capture the attention of researchers in Oman towards moving beyond

observational research to lifestyle interventional studies within the management of diabetes.

### 10.9.2 Weaknesses:

Despite efforts to minimise bias during the stages of project planning, implementation and reporting of findings, one should acknowledge that 100% elimination of bias is not possible. Some of the potential biases expected within studies of this thesis are described below.

#### *Selection bias*

Generalizability of the research findings may not be possible. The provision of routine diabetes care varies between health care centres in Oman, therefore the findings from this study may not reflect those of other countries or other regions of Oman. However, many of the findings may still be applicable to other health care systems.

#### *Measurement bias*

The 16-item GPAQ was developed by the WHO to measure PA (intensity, duration, and frequency) performed in three domains —work, transport and leisure as well as total sitting time, across different populations in the Western countries (Bull et al., 2009, Armstrong and Bull, 2006). However, validity and reliability testing did not include populations from the Arab world (see Sections 7.5.2 and 8.4). This indicates that results obtained on PA levels may be biased (a common weakness in PA questionnaire use) (Alghafri et al., 2018, Alghafri et al., 2017c). However, this tool has been widely used in WHO STEPwise surveys and National health surveys in many Arabic speaking countries including Oman (World Health Organization, 2005) and thus It would be useful to validate the GPAQ for this population using objective measures.

Similarly, the subjective nature of the two questionnaires used in the quantitative analysis (formative and main study) did not explicitly provide

guidance to the interviewee on potentially confusing phrases (i.e., ‘moderate-intensity physical activity’, ‘sitting time’, ‘environmental barriers’ and ‘lack of will power’). This may have led some people to misreport their PA levels, sitting time and PA barrier categories. Hence, limitations on using subjective measurement tools need to be addressed in order to improve future PA surveys in Oman or the Arab countries. However, this limitation was minimised by having the questionnaires interviewer led by trained POs.

Notably, the associations between the sociodemographic factors and meeting the PA recommendations or change in PA levels reported in the formative work (see Chapter 4, Section **Error! Reference source not found.**) or the main study (see Chapter 8, Section 7.4.3) do not denote causality due to the cross-sectional nature of the study. Future studies may consider intervention designs using objective PA measurement tools.

Another limitation is the absence of an in-depth qualitative exploration for capturing and exploring patients’ views on the possible PA methods in diabetes primary care clinics. Current views from patients were gathered within the items of the quantitative survey (open ended questions) to suggest ways to include PA in diabetes clinics. Furthermore, the FGDs targeted health care professionals only and it would’ve been useful to include another group discussion with patients, which would be particularly useful for patients with low literacy levels who may have found questionnaires difficult.

Despite frequent revisions of the translated questionnaires used in the “MOVEdiabetes” study by a professional medical translation company “Almaani Company”, 100% match of terms from English to Arabic cannot be guaranteed. The terms used to describe, quantify and measure PA are challenging. Additionally, the complex terms used to enhance self-efficacy and social support may be altered when translated from English to Arabic language.

Translating the PA guidelines of 150 minutes of moderate to vigorous PA/week to the public has been cited as sub-optimal in several recent studies (Weggemans et al., 2018, Weed, 2016). More evidence is required to find

effective ways to communicate PA to the public including PA per week vs per day, and the addition of muscle strength and balance exercises. This may be challenging for patients who are physically challenged through chronic disease (such as the participants of the “MOVEdiabetes” study) or disabilities making it difficult to engage in the recommended levels of PA. Evidence around light daily PA such as housework in patients with T2D is limited. Recent studies have suggested that light-intensity PA (e.g housework) has positive effects on obesity, markers of lipid and glucose metabolism, and mortality (Füzéki et al., 2017). Hence, inactive or insufficiently active people should be encouraged to engage in PA of any intensity. This is an important consideration given the fact that the majority of females in the studies of this thesis were housewives and thus most of their light-intensity activity was not captured in GPAQ (see Section 4.5.6). Future longitudinal studies are required to re-visit the current PA recommendations. In addition, PA measurement tools may be restructured to include light-intensity activities, at least for currently inactive populations (Hamasaki, 2016).

### *Response bias*

The majority of the outcome data related to PA, general wellbeing, PA influencers and exit surveys were based on reported perceptions, which may be influenced by socially desirable responses (social desirability bias) as these questionnaires were interviewer led. Future exit surveys could be anonymised instead to overcome this barrier.

Response bias from participants of studies in the thesis due to the expected positive relationship between the participant and the POs that may have influenced their insights (Grimm P, 2010) (see Section 7.5.2).

In real settings the face-to-face consultation offers participants a highly tailored intervention, which may particularly benefit people with T2D who require greater support. While they have been shown to be effective, consultations typically have duration of  $\geq 30$ -mins, which is relatively resource-intensive and may limit widespread implementation in practice leading to identical/similar responses



known as habituation bias. Hence, exploring the feasibility for group settings may be useful in primary care setting (Deakin et al., 2005).

The graphical presentation (yellow is sitting, green is standing and red is active) were used as an educational tool which may have helped to motivate participants to make changes and see progress. These images could have influenced subjects' responses to questions related to their PA behaviour introducing bias.

### *Researcher bias*

Despite extensive formative work to inform the "MOVEdiabetes" intervention 'cultural bias' cannot be fully excluded as the intervention methods were mostly from the West. Notably a complete cultural relativism is never 100 percent achievable.

Additionally, as most of the work presented in this thesis is interviewer led, leading questions and wording bias may have been introduced. This is a possibility as researchers/POs may have attempted to summarise what the respondents said without taking the conversations further.

Due to the fact that the participants' were familiar with their POs in their respected health centres, responses may have been influenced by pre-existing positive impressions and thoughts on health care providers (halo effect). For example, participants may have rated consultations positively overall due to their positive opinions on the POs delivering them.

Finally, changes in participants' medication (type and doses) over 12 month was not recorded which could have provided more evidence on the effects of the "MOVEdiabetes" intervention on treatment plans and possible reduced need for medications. On the other hand, changes in medication could've affected the motivation of the participants' to perform PA ( not studied in this project) and thus bias cannot be excluded.

*Reporting bias*

Given the nature of the low retention rates in studies within real clinical settings, the estimated recruitment and retention rates in the current study may have been calculated ambitiously. Future similar studies may attempt to have a larger sample size to ensure adequate retention rates (see Section 7.5.2).

Additionally, various attempts have been made to overcome the effects of the reporting (results) biases, including careful calculations of recruitment, retention and attrition rates along with statistical adjustments to the results presented within the published sub-studies in this thesis project.

**10.10 Future research**

Findings from this thesis project and discussions within the various chapters point towards the need for future research in several related areas.

Results from Chapters 4 and 8 indicated prolonged sitting time in adults with T2D. Prolonged sitting time and sedentary behaviour has been linked to 112% greater relative risk of developing T2D and metabolism of lipids and glucose in individuals with T2D (Ekelund et al., 2016, Hamilton et al., 2014, Wilmot et al., 2012c). The findings from this thesis support the need for further research about this behaviour in Oman including ways to reduce this hazard and ultimately control the high rates of non-communicable diseases.

The WhatsApp phone application was used in this thesis study to deliver motivational messages. However, greater insight is required from participants to understand the impact of such interventions in changing PA behaviour, promoting social support for PA, developing peer-motivation and exchanging of experiences. Additionally, the advantages of group vs individual based WhatsApp communications needs to be explored and compared.

Based on the methods available within the time, funding and manpower constraints of this study, measures were repeated at three different times, at baseline, 3 and 12 months. Results could have been more informative if outcomes were also repeated at six months and if the study follow up was for > one year. The long term (> one year) impact of the personalised PA “MOVEdiabetes” consultation in adults with T2D is needed to evaluate if PA behaviour change is maintained for longer than 12 months, whether further ‘top up’ of intervention input might be required, and to ensure that the elicited clinical benefits are preserved and more positive outcomes are achieved.

Future PA trials can, in addition to subjective PA measurement tools, be powered on PA levels determined by objective measures of physical activity (e.g. using accelerometer data). This would add to the current limited literature on the accurate PA behaviour (PA and sedentary behaviour) of the Arab population.

Based on the fact that lack of will power and social support for PA was highly rated as barrier to performing PA (see Chapter 4, Section **Error! Reference source not found.**), it is important to use appropriate tools to enhance self-efficacy, motivation and determination for PA and provision of social support (see Chapter 9, Section 8.4). Future exploration on culturally feasible psycho-social scales may be warranted as the “MOVEdiabetes” scale for social support had poor internal consistency score (see Section 8.3.2).

Evaluating the optimum frequency for the PA consultations may be required. This evaluation introduces the importance of tailoring the number of consultations to individual needs especially in individuals who are more vulnerable to being inactive.

Given the high prevalence of diabetes, it may be wise to introduce this intervention at diagnosis or even as a preventive strategy for individuals at high risk of diabetes.

Finally, evidence around the importance of the integrative approach in delivering care for adults with T2D is consistent. However, lack of time, busy clinics and having to manage other comorbidities may tempt the health care providers to drop PA from their consultation plans. Hence, options for stand-alone PA consultations/clinics, where patients could be referred to, may be worth investigating.

### **10.11 Conclusions**

The body of research reported in this thesis has generated new evidence for a part of the world for which there is limited published research evidence on appropriate PA promotion in diabetes care.

Findings from the formative/exploratory studies showed low levels of PA (particularly in females compared to males) and long sitting time in adults with T2D in Oman. The main barriers to performing PA were lack of willpower, resources and social support. Walking was the preferred PA by both the participants and health care providers.

Health care providers perceived the personalised face to face consultations delivered by dietitians as the most appropriate method to promote PA in the current diabetes care. This approach was additionally augmented by welcoming the use of pedometers and WhatsApp phone application in primary care local setting.

The results from this research demonstrated that the personalised face to face PA consultations (delivered by trained dietitians), use of pedometers, WhatsApp phone application and behaviour change techniques were effective in promoting PA behaviour change in adults with T2D. The consultations were personalised taking account of individuals' specific needs, including gender, opportunities within daily life to promote active behaviour and readiness to change. Behaviour change techniques including enhancing self-efficacy and providing opportunities

for social support seemed to be valuable in delivering effective PA consultations.

Confirming the evidence around benefits of PA in diabetes management, this multi-component intervention had favourable effects on several cardio-vascular, general health, and quality of life outcomes. Additional metabolic positive changes namely weight and Hba1c, were shown within the intervention group.

The current thesis provides potential insights for engaging existing health professionals with significant effect on extending their roles to deliver PA consultations into everyday practice. The PA training of health care workers within this project offer a great potential for capacity building in this area and further integration of PA.

The intervention components used in this project were acceptable by both the participants and POs indicating that the “MOVEdiabetes” project was culturally appropriate and can be developed, delivered and successfully assessed in people attending diabetes clinics in primary care. To enhance the magnitude of impact, future research designs may consider interventions at multiple levels (environmental, sectoral, and individual). More information is needed regarding strategies to promote the maintenance of behaviour change, appropriate recruitment strategies to target individuals who are inactive, and multi-collaborative approaches to promote PA.

Additionally, this work provides a strong basis for exploring further areas namely the sedentary behaviour of the Omani adults with T2D and its association with the metabolic risk factors.

Finally, it is hoped that this research will help to inform current practices of the Omani Ministry of Health for the use methods to promote PA presented in the “MOVEdiabetes” intervention as an integral part of diabetes primary care.

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**Appendices**

### Appendix 3.1: Barriers and facilitators to PA among patients at high risk of diabetes or with diabetes

Reference	Country	Aim of study	Method	Findings	Limitations
Obese T2D patients  Egan et al. (2013)	Dublin city	To assess exercise habits in obese Irish patients with T2D to determine if they were adhering to exercise guidelines and to identify perceived barriers to exercise.	self- administered questionnaire to obese patients with T2D attending routine outpatient diabetes clinics at a public teaching hospital  N=145	Barriers to PA were: physical discomfort, exercise being too boring and having no time to exercise, too tired, weather disliking the gym, being too depressed, PA being too expensive, having negative past experiences, being embarrassed about physical appearance, having nobody to exercise with, transport issues, the roads being too dangerous and a lack of support from family/friends.  On the other hand, pet owners had positive associations with performing PA.	Findings may not be generalised.
T2D in relation to self-management of dietary intake and PA compared with that of health professionals (HPs)	UK	To explore the views of individuals recently diagnosed with T2D in relation to self-management of dietary intake and	qualitative study (focus groups were held with patients and in-depth semi-structured interviews with HPs	Difficulty changing well-established habits, negative perception of the 'new' or recommended regimen, barriers relating to social circumstances, lack of knowledge and understanding, lack of motivation and barriers relating to the	Views presented in this study may not be representative of all recently diagnosed patients.

Reference	Country	Aim of study	Method	Findings	Limitations
in primary and secondary care  Booth et al. (2013)		PA, and to compare these with the views of health professionals (HPs).	Patients: n = 16 female, aged 45-73 years  HPs: n = 7	practicalities of making lifestyle changes	
Obese T2D patients  Labrunée et al. (2012)	France	To assess, in obese T2D, the impact of a home-based effort training program and the barriers to PA.	Randomized control study randomized to either a control group (CG), or an intervention group (IG) performing home-based cyclergometer training during 3 months, 30 min/day, with a monthly-supervised session.  The initial and final measurements included several physiological, biometric, blood tests and quality of life assessment. Also, a long-term assessment of the amount of PA and the barriers to PA practice was conducted using a questionnaire by phone call.	Perception of a low exercise capacity, a poor tolerance to effort, lack of motivation and the existence of pain associated to PA	Selection bias linked to the mode of recruitment of patients.  Results cannot be generalized to the whole population presenting with T2D.  Absence of objective PA measurement tools.

Reference	Country	Aim of study	Method	Findings	Limitations
			N= 23		
High risk of T2D  Korkiakangas et al. (2011)	Finland	To describe motivators and barriers to exercise among adults with a high risk of T2D	Qualitative study on data gathered from video-recorded group counselling sessions related to exploring the Effectiveness and Feasibility of Activating Counseling Methods and Videoconferences in Dietary Group Counseling  N= 74 subjects	Weather/season, health problems, lack of time, work related factors and lack of interest as the main barriers to exercise  Supporters for PA were enjoyment from exercise, social relationships related to exercise, encouragement from others, benefits to health, and the aim of weight control.	It is possible that the presence of cameras had some influence on discussions.
Adults with and without abnormal glucose metabolism (AGM)  Hume et al. (2010)	Australia	To examine perceived barriers to PA among adults with and without abnormal glucose metabolism, and whether barriers varied according to PA status	Population-based cross-sectional study (The Australian Diabetes, Obesity, and Lifestyle) among adults aged $\geq 25$ years  N= 7088 participants	Lack of time, other priorities, and being tired	The self-reported nature of PA levels and the cross-sectional design of the study.



Reference	Country	Aim of study	Method	Findings	Limitations
High risk adults and T2D patients  Korkiakangas et al. (2009)	Finland	To identify the reported barriers to regular exercise among adults either at high risk or already diagnosed with T2D	Systematic review  N= 13 research articles  (9 quantitative and 4 qualitative)	Internal barriers:  Shame, laziness, fear of exercise, and difficult life situations, poor health, and overweight and overweight subjects often found exercise uncomfortable, and lack of time either due to official work or home duties as the reason.  External barriers: Weather, cultural factors, lack of exercise facilities, and lack of social support.	Limited generalisability
Mexican Americans with T2D  Mier et al. (2007)	USA	To examine perceptions of PA (motivators and barriers) in a population of Mexican Americans who have T2D.	Qualitative research via six focus groups of Mexican Americans with T2D. N=39 Mexican Americans	Lack of time, physical pain depression, being overweight, unsafe neighbourhoods, and lack of facilities.  Facilitators for PA were linked to family support and the sense of well-being derived from PA	Limited generalisability
South Asian British  Lawton et al. (2006)	UK	Patients' perceptions and experiences of undertaking PA as	Qualitative study (single and in-depth interviews) of patients from five General Practices in Edinburgh.	Lack of time, cultural norms and social expectations	Limited generalisability

Reference	Country	Aim of study	Method	Findings	Limitations
		part of their diabetes care	Pakistani (n = 23)  Indian (n = 9) patients'		
High-risk adults who attended primary care family practices  Donahue et al. (2006)	North Carolina	To describe PA habits, and barriers.	A cross-sectional study of high-risk adults who attended 14 North Carolina primary care family practices. Participant were mailed a survey about PA barriers.  N= 522	Low priority, worried about injury and difficulty finding time were the main barriers to PA	
Patients with diabetes  Thomas et al. (2004)	UK	To identify how much PA do patients with diabetes perform and their perceived factors that prevent them from doing more PA?	Interview based questionnaire distributed to patients attending the Diabetes Clinic, Ninewells Hospital, Dundee over a period of five months  N= 406 patients	Difficulty taking part in exercise, tiredness, being distracted by something good on television, lack of time and lack of local facilities	The self-reported nature of PA levels and limited generalisability
African Americans with T2D attending	USA	To determine PA preferences and barriers to exercise in an urban	A survey (self-administered questionnaire) of all patients attending the	Pain Increasing age, body mass index, college education and being a	The self-reported nature of PA levels

Reference	Country	Aim of study	Method	Findings	Limitations
<p>diabetic clinic for the first time</p> <p>Wanko et al. (2004)</p>		diabetes clinic population	<p>clinic for the first time. Evaluation measures were type and frequency of favorite leisure-time PA, prevalence and types of reported barriers to exercise, and analysis of patient characteristics associated with reporting an obstacle to exercise.;</p> <p>N= 605</p>	<p>smoker increased the odds to reporting a barrier.</p> <p>Male participants were more facilitated to perform PA compared to women</p>	

### Appendix 3.2: Summary of studies of barriers to PA in the Arab world including Oman

Reference	Country	Aim of study	Method	Findings	Limitations
<p>Addressing physical inactivity in Omani adults: perceptions of public health managers.</p> <p>Mabry et al. (2014b)</p>	Oman	To explore barriers and solutions to addressing physical inactivity and prolonged sitting in the adult population of Oman.	Qualitative study involving semi-structured interviews with ten mid-level public health managers.	Barriers for physical inactivity were grouped around four themes: (i) intrapersonal (lack of motivation, awareness and time); (ii) social (norms restricting women's participation in outdoor activity, low value of physical activity); (iii) environment (lack of places to be active, weather); and (iv) policy (ineffective health communication, limited resources). Solutions focused on culturally sensitive interventions at the environment (building sidewalks and exercise facilities) and policy levels (strengthening existing interventions and coordinating actions with relevant sectors). Participants' responses regarding sitting time were similar to, but much more limited than those related to physical inactivity, except for community participation and voluntarism, which were given	Restriction of the sample to mid-level public health programme managers.

Reference	Country	Aim of study	Method	Findings	Limitations
				greater emphasis as possible solutions to reduce sitting time.	
Measuring stages of change, perceived barriers and self-efficacy for physical activity in Saudi Arabia.  Al-Otaibi (2013)	KSA	To investigate the present status of physical activity among Saudi adults in Al-Ahsa, and to examine the association between the stages of change for PA and perceived barriers, and self-efficacy.	A cross- sectional study of 242 subjects (118 males and 124 females) attending health centres aged between 20-56 years, were personally interviewed for demographic data, anthropometric measurement, PA, stages of change for PA, self-efficacy and perceived barriers to PA.	48% females vs 16.9% of males were overweight or obese with no significant difference between the genders for BMI categories. Males were significantly more physically active than females ( $P=0.007$ ). 20% of the males were in maintenance stage, while similar percentage of the females were in contemplation stage. Males had a higher mean score of self-efficacy and less external barriers of PA. The major barrier among the females was lack of time and in the males, lack of motivation. The females had less internal barriers comparable to the males.	Small number of subject may not be representative of the general Saudi population. Expected misclassification in PA behaviour due to the self-reporting nature of the study.
Qatari women living with cardiovascular diseases- challenges and opportunities to engage in healthy lifestyles.  (Donnelly et al., 2012)	Qatar	To investigate ways to increase participation in PA.	(Qualitative study) Individual in-depth interviews were conducted with 50 Arabic women.	Social support networks, cultural values, religion, changing socio-demographic and economic conditions, heart disease, and a harsh climate affect the ability of these women to pursue a healthy lifestyle.;	Results cannot be generalized.

Reference	Country	Aim of study	Method	Findings	Limitations
Pattern, prevalence, and perceived personal barriers toward physical activity among adult Saudis in Al-Hassa, KSA.  Amin et al. (2011)	Al-Hassa, KSA	To determine patterns of physical activity (PA) along domains of work-transport-leisure and perceived personal barriers to leisure-time-related physical inactivity.	A cross-sectional study in which 2176 adult Saudis attending urban and rural Primary Health Centres.  Participants were personally interviewed to gather information regarding socio-demographics, PA pattern using Global Physical Activity Questionnaire (GPAQ), and perceived barriers toward recreation-related PA.	52% of subjects were sufficiently active meeting the minimum recommendations when considering total PA and 21% of the subjects were sufficiently active in leisure-time-related activity. Regression analyses showed that females, higher educational and occupational status were negative predictors to total and leisure-related PA. Barriers perceived toward leisure-related PA included weather, traditions, lack of facilities and time.	Results of this study cannot be generalized  Possibility of recall bias cannot be ruled out.  GPAQ only considers work-related domain without much differentiation between domestic and other forms of occupational-related activity.
Barriers and facilitators of weight management: perspectives of Arab women at risk for type 2 diabetes.	UAE	To explore weight management behaviours and perceptions of women who are at increased risk	Qualitative study through eight focus group interviews.	A number of personal, social and physical environmental themes emerged as both barriers and enablers that are consistent with the social ecological model of health promotion. Low motivation, lack of	Only 75 Emirati women were included on their weight, thus limiting the capacity to extrapolate these

Reference	Country	Aim of study	Method	Findings	Limitations
*Ali et al. (2010)		for type 2 diabetes.		social support, competing demands, lack of culturally-sensitive exercise facilities and sociocultural norms that restrict outdoor physical activities were the main barriers cited by the participants. On the other hand, social support, such as having other women to walk with, helped them stay physically active.	findings to Emirati women.
Giving young Emirati women a voice: participatory action research on physical activity.  Berger and Peerson (2009)	UAE	To assess PA levels among, identify social and cultural barriers to PA, and recommend strategies to increase PA.	(Qualitative research)  Semi-structured in-depth interviews and focus groups with young Muslim women in collage.	Perceived barriers to daily exercise included: gender and age; role models; culture; climate; clothing and make-up; personal motivation, time and opportunity; and school and government policies. The UAE climate can be both an enabler and an obstacle to PA levels.	Small sample size.  Cross-cultural communication in English and Arabic may also have influenced data collection.
Barriers to a healthy lifestyle among patients attending primary care clinics at a university hospital in Riyadh.  AlQuaiz et al. (2009)	KSA	To identify barriers to physical activity and healthy eating among patients attending primary health care clinics in Riyadh city.	A cross-sectional study at King Khalid University via a questionnaire about barriers to physical activity and healthy eating was adapted from the CDC web site.	The prevalence of physical inactivity among the Saudi population in the study was 82.4%). Females were more physically inactive compared to males ( $P<.001$ ). The most common barrier to PA was lack of resources, which was significantly higher among females than males and among the	All subjects in the study were from the city of Riyadh.  Difficult to draw conclusions about causation.

Reference	Country	Aim of study	Method	Findings	Limitations
				lower income versus the higher income group.	
Physical activity and reported barriers to activity among type 2 diabetic patients in the United Arab Emirates.  *Al-Kaabi et al. (2009)	UAE	To assess PA practice among type 2 diabetic patients.	A cross-sectional study (interviewer-administered questionnaire) of type 2 diabetic patients (390) recruited from the outpatient clinics in Al-Ain District, during 2006.	Only 25% reported an increase in their PA levels following the diagnosis of diabetes, and only 3% reported PA levels that meet the recommended guidelines. The majority of reported barriers to PA were disease (e.g. arthritis), lack of time, cultural issues, lack of interest, and family responsibilities. Physicians were reported to be the best source of advice regarding PA compared with diabetic educators. The total number of barriers reported was positively correlated with BMI and systolic blood pressure and was negatively correlated with HbA1c, and triglycerides.	Self-reporting.  All subjects in the study were from the city of Al Ain.  Difficult to draw conclusions about causation.
Cultural factors and patients' adherence to lifestyle measures.  *Serour et al. (2007)	Kuwait	To measure adherence and barriers of complying with lifestyle recommendations among patients with high	334 Kuwaiti adult males and females with hypertension, T2D, or both, completed a routine clinic visit in one of the selected six family practice centres.	63.5% of patients reported that they were not adhering to any diet regimen, 64.4% were not participating in regular exercise,  90.4% were overweight or obese. The main barriers to adherence to exercise were lack of time (39.0%),	The study was conducted  in only six family practice health centres out of 74



Reference	Country	Aim of study	Method	Findings	Limitations
		cardiovascular risk factors.	Trained staff used a structured questionnaire to obtain the required data.	coexisting diseases (35.6%), and adverse weather conditions (27.8%). Factors interfering with adherence to lifestyle measures among the total sample were traditional Kuwaiti food, which is high in fat and calories (79.9%), stress (70.7%), a high consumption of fast food (54.5%), high frequency of social gatherings (59.6%), abundance of maids (54.1%), and excessive use of cars (83.8%).	general practice health centres in Kuwait

\* Studies involve participants at risk or with T2D

### Appendix 3.3: Common behaviour change theories

Theory name	Definition	Key concepts
Social cognitive theory (SCT) and self-efficacy  (Annesi et al., 2013, Wilcox et al., 2008, Hallam and Petosa, 2004, Bandura et al., 1977)	Behavioural change through the principle of interchanging elements: environmental (physical, social and cultural), personal (emotional, personality, cognition and biology), and behavioural (past and current achievement).	Reciprocal determination  Behavioural capability  Self-efficacy  Outcome expectations  Observational learning  Reinforcement
Trans-theoretical model (TTM)  (Reed et al., 1997, Prochaska et al., 1992, Marshall and Biddle, 2001)	Includes five stages of change that explains different level of readiness from inactive to active.	Pre-contemplation (not ready)  Contemplation (getting ready to be regularly active in the next 6 months)  Preparation (ready to be regularly active in the next 30 days)  Action (regularly active for <6 month)  Maintenance (regularly active for ≥6 months)
Health belief model (HBM)  (Kiviniemi et al., 2007)	Hypothesizes that readiness to act is influenced by individuals' beliefs on susceptibility to disease, and perceptions of the benefits.	Perceived susceptibility  Perceived severity  Perceived benefits  Perceived barriers  Cues to action  Self-efficacy
Self-determination theory (SDT)  (Silva et al., 2010)	Underpins three primary psychosocial needs that have to be satisfied to create change in PA behaviour where motivation is the core of this theory.	Self-determination or autonomy Demonstration of competence or mastery Relatedness or ability to experience meaningful social interactions with others

Theory name	Definition	Key concepts
Theory of Planned Behaviour (TPB)  (Kinmonth et al., 2008)	A theory about the link between beliefs and behaviour directed towards favourable health-related behavioural intention.	Behavioural beliefs  Normative beliefs  Control beliefs
Ecological perspective (Sallis et al., 2006)	A multi-level model of PA influences along the life course. The model is ecological because of the inter-relations between individuals and their social and physical environments.	Multiple levels of influence Intrapersonal  Interpersonal  Institutional  Community  Public policy
Behaviour Change Wheel  (BCH)  (Michie et al., 2011a)	A multi-level approach based on three criteria: comprehensiveness, coherence, and a clear link to an overarching model of behaviour.	The centre of the proposed BCW is a 'behaviour system' involving three essential conditions: capability, Opportunity, and motivation.  Around them are the nine intervention functions aimed at addressing deficits in one or more of these conditions; around this are placed seven categories of policy that could enable those interventions to occur.

## Appendix 4.1: Published study (1) “Correlates of physical activity and sitting time in adults with type 2 diabetes attending primary health care in Oman

Alghafri et al. *BMC Public Health* (2018) 18:85  
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### RESEARCH ARTICLE

### Open Access



## Correlates of physical activity and sitting time in adults with type 2 diabetes attending primary health care in Oman

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### Abstract

**Background:** Despite evidence of the benefits of physical activity in the management of type 2 diabetes, it is poorly addressed in diabetes care. This study aimed to identify the prevalence and correlates of meeting  $\geq 600$  MET-min/wk (150 min/wk) of physical activity and sitting time in adults with type 2 diabetes in Oman. Approaches to encourage physical activity in diabetes care were explored.

**Methods:** A cross-sectional study using the Global Physical Activity Questionnaire was conducted in 17 randomly selected primary health centres in Muscat. Clinical data including co-morbidities were extracted from the health information system. Questions on physical activity preferences and approaches were included. Patients were approached if they were  $\geq 18$  years, and had been registered in the diabetes clinic for  $> 2$  years.

**Results:** The questionnaire was completed by 305 people (females 57% and males 43%). Mean age (SD) was 57 (10.8) years and mean BMI (SD) was 31.0 (6.0) kg/m<sup>2</sup>. Duration of diabetes ranged from 2 to 25 (mean 7.6) years. Hypertension (71%) and dyslipidaemia (62%) were common comorbidities. Most (58.4%) had an HbA1c  $\geq 7\%$  indicating poor glycaemic control (55% in males vs 61% in females).

Physical activity recommendations were met by 21.6% of the participants, mainly through leisure activities. Odds of meeting the recommendations were significantly higher in males (OR 4.8, 95% CI 2.5–9.1), individuals  $\leq 57$  years (OR 3.0, 95% CI 1.6–5.9), those at active self-reported stages of change for physical activity (OR 2.2, 95% CI 1.2–4.1) and those reporting no barriers to performing physical activity (OR 2.7, 95% CI 1.4–4.9).

Median (25th, 75th percentiles) sitting time was 705 (600, 780) min/d. Older age ( $> 57$  years) was associated with longer sitting time ( $> 705$  min/d) (OR 2.8, 95% CI 1.7–4.6).

Preferred methods to support physical activity in routine diabetes care were consultations (38%), structured physical activity sessions (13.4%) and referrals to physical activity facilities (5.6%) delivered by a variety of health care providers.

**Conclusions:** The results suggest that intervention strategies should take account of gender, age, opportunities within daily life to promote active behaviour and readiness to change. Offering physical activity consultations is of interest to this study population, thus development and evaluation of interventions are warranted.

**Keywords:** Physical activity, Type 2 diabetes, Primary health care, Correlates, Sitting time, Consultations, Oman

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## Background

In 2013, the International Diabetes Federation (IDF) estimated that 8.3% of the global population have diabetes (382 million) of which 90% have type 2 diabetes (T2D) [1]. The number of people with diabetes is expected to increase by 55% (to 592 million) in 2035. In countries of the Middle East and North Africa (MENA) region, the negative impact of diabetes on health care system expenditures, population productivity and quality of life is of great concern, especially in the Arab countries of the Gulf Cooperation Council (GCC) where prevalence of diabetes is high [2]. Saudi Arabia, Kuwait and Qatar were reported by the IDF in 2013 to be within the top 10 countries with the highest prevalence of diabetes (24.0%, 23.1% and 22.9% respectively) [1, 3]. Oman, similar to the other high income GCC countries, has gone through rapid economic development leading to consumption of energy dense diets and sedentary lifestyles [4]. In Oman, diabetes prevalence increased from 8.3% in 1991 to 12.3% in 2008 and the current estimate reported by IDF is 14.2% [1, 5]. Management of diabetes in Oman and other GCC countries is a public health concern as the countries of the MENA region are estimated to have a 96% increase in number of people with diabetes by 2035 [1].

Physical inactivity is estimated as being the principal cause for 27% of diabetes, and 30% of ischemic heart disease. Similarly, greater sitting time is considered an independent risk factor for diabetes, cardiovascular disease, and all-cause mortality [6]. Sitting more than 8 h/day leads to increase risk of all-cause mortality even among individuals achieving the recommended 150 min/wk. of physical activity (PA). As such, addressing low levels of activity and sedentary behaviours are required to reverse this trajectory.

Evidence for the positive effects of PA on individuals with diabetes is consistent. PA for 150 min a week has been shown to increase insulin sensitivity, lower blood sugar levels, reduce body fat and improve general health [7]. However, in western countries, mainly United States of America (USA), over 60% of patients with diabetes don't meet the recommended levels of PA [8]. This is similar to the proportion of adults from the general population in Arabic countries including the GCC countries where it was reported that only 39.0% to 42.1% of men and 26.3% to 28.4% of women meet recommended levels of PA [9]. However, in Oman, reported activity levels are lower. The 2008 Oman World Health Survey, reported that only 15.0% of patients with T2D meet PA recommendations of 150 min a week of moderate to vigorous activity [5]. In Sur (north-east coast of Oman), correlates for physical inactivity in the general population ( $n = 1373$ ) were reported using the Global Physical Activity Questionnaire (GPAQ) [10]. Inactivity (<600MET-min/wk)

in men increased with age and Body Mass Index (BMI); with every unit of BMI increase the travel inactivity increased by 6.0%. Higher odds of leisure inactivity were seen in males with lower levels of education, individuals who were not employed and married individuals. Women aged  $\geq 40$  years had more than double the odds of being inactive compared with the youngest in travel inactivity and the odds of leisure inactivity were approximately 1.8-fold higher in employed women versus unemployed. In the same study, reported mean sitting time was 120 min/d [11] which is considerably low compared with mean sitting time of >270 min/d in Saudi Arabia [12] and >220 min/d in Kuwait [13]. Nonetheless, evidence on sitting time patterns in sub-groups of populations (including people with diabetes) in the Arab world is scarce, but is a potential area of concern.

Socio-demographic, psychosocial and environmental factors have been reported to be associated with PA patterns in populations with T2D, but these associations vary widely across studies [14–16]. Consolidated evidence on levels and correlates of PA and sitting time in Arab countries (especially the countries of the GCC) has never been explored despite the socio-cultural and environmental differences, which are likely to influence behaviour and activity levels.

The present study aimed to collect preliminary data to inform a PA intervention design in diabetes primary care. To do so, the study aimed to describe the PA patterns of adults with T2D and examine the sociodemographic factors, physiological factors and perceptions of PA associated with meeting the World Health Organization's recommended PA levels of  $\geq 600$  MET-min/wk. [10], and prolonged sitting time. Secondly, it aimed to identify views for integrating PA in routine diabetes care within local primary health care (PHC) setting.

## Methods

A cross-sectional interview based survey was conducted during April and May 2015 in Muscat, Oman using the GPAQ [17]. Omani patients with T2D attending their routine diabetes clinics in 17 randomly selected centres of PHC were invited to participate. Inclusion criteria were: age  $\geq 18$  years, under diabetes clinic care for more than 2 years and ability to provide informed consent. For illiterate participants, informed consent was taken from their spouse, son, daughter or other close family member after verbal discussions and approvals from the concerned participants. Participants with type 1 diabetes, newly diagnosed patients (due to incomplete data in the electronic health information system), those who had difficulty in performing any PA (due to physical disabilities), those with a history of myocardial infarction of <6 months, or with multiple organ failure, were excluded.

### Sample size

The sample size was calculated using an estimated 15% prevalence of meeting the PA recommendations in patients with diabetes as reported previously in the 2008 Oman World Health Survey [18]. For 95% confidence limits, a response rate of 80%, and a precision of 20%, the calculated sample size was 305 participants over Muscat, the capital of Oman and where 50% of the Omani population live. Muscat region has a total of six urban willayats “districts” (Seeb, Bausher, Amirat, Qryat, Muttrah and Muscat) which were all included in the study.

### Data collection tool

A multi-section questionnaire was designed to collect the following data through interviewing the participants:

#### Socio-demographic data

Multiple choice questions on gender, willayat, age, marital status, education, household income and work status.

#### Perceptions on stages and status of physical activity

A scale developed by Martin et al. [19] was used to report stages of PA based on the trans-theoretical theory of behaviour change. Subjects who were participating in moderate physical exercise five or more times per week or in vigorous exercise three to five times per week longer than six consecutive months were categorized to “Maintenance stage” or if it was less than 6 months to “Action stage”. “Preparation stage” was for subjects who were thinking about starting exercise or walk in the near future, or who were doing vigorous exercise less than three times per week, or moderate physical exercise less than five times per week. Contemplation stage “getting ready” was for subjects who were thinking about starting PA including walking in the next 6 months. Subjects who were not thinking about starting any PA in the near future were categorized as Pre-contemplation stage “not ready”. In addition, participants were asked to answer “yes” or “no” to the questions “have you received any PA advice in the past six months within their diabetes care by the diabetes care team in the health centre?”, “do you think you are performing sufficient PA?”, and “do you perceive any barrier to performing PA?”. Participants were further asked to describe any perceived barriers to their participation in PA. Detailed results for Barriers to performing PA in this population is presented elsewhere. [20].

#### Levels of physical activity and sitting time

The 16 item GPAQ was developed by WHO for PA surveillance and is used in more than 100 countries globally [17]. It estimates PA (intensity, duration, and frequency) performed in three domains - work (paid and unpaid including housework), travel (walking and cycling) and leisure, which includes total sitting time. PA was

estimated by calculating energy expenditure using the Metabolic Equivalent (MET), the ratio of specific PA metabolic rates compared with the resting metabolic rate (one MET is equivalent to the energy cost of sitting quietly, kcal/kg/h). Total MET-min/d was calculated for each domain by first multiplying MET values by reported minutes (moderate-intensity and transport activity assigned 4MET values and vigorous-intensity activities assigned 8MET values), then adding the total MET-min of vigorous and moderate intensity activities performed [17].

Estimated weekly PA levels (including activity for work, during travel and leisure time), were compared against WHO PA recommendations of 150 min of moderate-intensity PA or 75 min of vigorous-intensity PA per week (which equates to an equivalent combination of moderate- and vigorous-intensity PA achieving at least 600 MET-min/wk. [10].

A single open-ended question regarding total sitting time is included in GPAQ as “Over the past seven days, how much time did you spend sitting or reclining on a typical day?” Subjects were requested to estimate their sitting time in minutes per day.

Additionally, information on physiological data (health status and anthropometric measures) were collected from the electronic health information system coinciding with diabetes including duration of diabetes, BMI, medication, blood pressure, lipid profile, and presence of any comorbidities defined as cardiovascular, hyperlipidemia, thyroid abnormalities, renal, eye, musculoskeletal, or any other recorded condition in the system.

Participants were also asked to select their preferred PA (from a list of walking, jogging, running, swimming, football, and others to be specified), and suggest PA intervention components to be integrated within routine diabetes clinics in PHC and who it should be delivered by in the health centre.

### Training

Health care staff were recruited for data collection and received training on conducting the interview. Before full-scale sampling began a pre-test with 25 participants from a population outside the sampled health centres was undertaken to evaluate face validity, ease of questioning and the length of time to administer the questionnaire. Study related data collection procedures, dynamics and tool were all modified accordingly.

### Ethical approval

Potential participants were invited to be interviewed for the survey when they entered the clinic or waited for clinical staff. All participants were provided with written information and provided informed consent prior to commencement of the interview. For illiterate individuals,

consents to participate in this study were provided by their accompanying support member (spouse, son or daughter) who could at least read and write.

#### Data collection, and entry

Quality of entered data was cross-checked by a nurse trained in quality assurance using check lists specific to the study in a sample of 10% of questionnaires selected at random.

Data entry, cross-checking and cleaning was done through Epi Info™ 7. Entered data was transferred to SPSS v21 for analysis according to GPAQ protocol [17].

#### Statistical analyses

Descriptive statistics were expressed as mean (SD), median (25th, 75th percentiles) or percentages and number of active cases for the total study population as appropriate. All statistical tests were two sided and at a significance level of 0.05. Bivariate relationships between the dependent variable of meeting WHO PA recommendations and the independent variables, namely socio-demographic (gender, region, age, marital status, education, income, and work status), physiological (BMI, medication, duration of diabetes, blood pressure, lipid profile, and reporting comorbidities), and self-reported perceptions of PA (self-reported levels of PA, receiving PA advice, self-perceptions performing sufficient PA/wk., reporting barriers to leisure PA), were tested by chi-square analyses. Potentially significant associations with  $P$  values  $<0.05$  were further analyzed using binary logistic regression. The categories of several variables were collapsed to ensure sufficient power for the regression models and adequate numbers in all categories. For example, age was dichotomised using mean value (in years) of  $\leq 57$  vs  $>57$ , married vs unmarried, educated vs uneducated, income  $<500$  or  $\geq 500$ , and active vs inactive self-reported stages of PA. Backward stepwise elimination was utilised to select the best model with significant variables that could best predict the behaviour of meeting PA recommendations. Initially all potential variables with significant  $P$ -values on chi-square test were included in the model. Variables with  $P$  values  $>0.05$  were dropped one by one until a significant model with the largest adjusted  $R^2$  criterion was reached and hence deemed to be the best model fit. The odds ratios were calculated for socio-demographic variables (against the reference categories of female, subjects aged  $>57$  years, currently married, educated, with income of  $\geq 500$  Omani rials, and employed), physiological variables (due to more participants numbers, the reference category was reporting existing comorbidities), and self-reported perceptions of PA (against the reference categories of reported inactive stages of PA ("not ready" and "getting ready") and reporting performing sufficient PA/wk. and reporting barriers to leisure PA).

Mann-Whitney U non parametric test was used to identify the association of sitting time with meeting PA recommendation. Whilst the literature is inconsistent on average, low and high sitting times for this population, sitting time was dichotomised around the median value ( $\leq 705$  min/d and  $>705$  min/d) to allow the determination of any correlates associated with this behaviour.

Preferences for PA, and the PA delivery components of interest to adult patients with T2D in health centres are reported as proportions of the population.

## Results

### Socio-demographic

During the study duration, 312 patients were invited to participate and 305 completed the questionnaire (98%), with slightly greater proportion of females than males (57.4% vs 42.6%). The majority of the sample was from Seeb willayat (41.7%), a highly populated region in Muscat. Mean (SD) age was 57 (10.8) years with more than two-thirds being married (78.8%) and almost half indicating they 'don't read or write' (48.9%). Thirty nine percent of subjects reported house hold income of  $<500$  Omani rials. Most females were housewives (77.0%). It was noted that more males than females were government employees (14.6% and 2.9% respectively) (Table 1). Meeting the PA recommendations was more common in males  $P < 0.001$ , unmarried individuals  $P = 0.004$ , those who completed higher education  $P = 0.030$ , and had an income of 500-  $<1000$  Omani rials  $P = 0.008$ , government employees  $P < 0.001$ .

### Physiological

Duration of diabetes extended from 2 to 25 [mean (SD) 7.59 (4.7) years, and median (range) 6 (23) years]. Eighty-nine percent of the sample were overweight or obese, with half classed as obese (50.2%) [mean (SD) BMI 30.96 (6.01)  $\text{kg/m}^2$ ]. More females were classed as obese compared to males (59.4% vs 37.7%), however, a greater proportion of males were overweight compared to females (44.6% vs 34.3%). The majority of subjects were on oral hypoglycaemic drugs compared to diet only (85.2% vs 14.8%) with a quarter using insulin in addition to the oral drugs (24.6%). Hypertension and dyslipidaemia were the most common comorbidities (71.1% and 62.0% respectively) (Table 2).

Over two-thirds of participants (71.0%) were using anti-hypertensive agents, of which most had normal BP readings (77.7%). Sixty-two percent were on statins of which the majority had fasting cholesterol (66.0%), HDL (83.0%), LDL (62.0%) and TG (67.0%) within recommended levels (as per the Oman diabetes management guidelines) [21]. Just over half the sample (58.4%) were found to have uncontrolled diabetes with HbA1c  $>7\%$ . Compared to males, there were significantly more

**Table 1** Sample characteristics (socio-demographic variables) and prevalence of meeting physical activity recommendations

Sample characteristics	Total sample <i>n</i> = 305(%)	Meeting physical activity recommendations <i>n</i> = 66 (21.6%)	<i>P</i> -value
Gender			<0.001*
Male	130 (43)	45 (35)	
Female	175 (57)	21 (12)	
Willayat			0.060
Alamirat	42 (14)	4 (10)	
Bousher	37 (12)	3 (8)	
Muscat	22 (7)	3 (14)	
Muttrah	63 (21)	23 (37)	
Quryat	14 (4)	2 (14)	
Aseeb	127 (42)	31 (24)	
Age categories (years)			0.050
< 40	21 (7)	10 (48)	
40–49	54 (18)	14 (26)	
50–59	98 (32)	24 (24)	
60–69	92 (30)	15 (16)	
≥ 70	40 (13)	3 (8)	
Marital status			0.004*
Unmarried	8 (3)	3 (38)	
Currently married	240 (79)	57 (24)	
Separated/divorced	20 (6)	5 (25)	
Widowed	37 (12)	1 (3)	
Education			0.030*
Don't read or write	149 (49)	18 (12)	
Less than primary	49 (16)	8 (16)	
Primary completed	28 (9)	8 (29)	
Preparatory completed	27 (9)	13 (48)	
Secondary completed	30 (10)	11 (37)	
College completed	10 (3)	4 (40)	
Higher education completed	11 (4)	5 (45)	
Income (Omani Rials)			0.008*
< 500	120 (39)	22 (18)	
500- < 1000	100 (33)	35 (35)	
1000- < 1500	17 (6)	4 (24)	
≥ 1500	14 (5)	3 (21)	
No answer	54 (17)	2 (4)	
Employment			<0.001*
Government employee	24 (8)	12 (50)	
Non-government employee	35 (11)	13 (37)	
Self-employed	12 (4)	4 (33)	
Retired	77 (25)	19 (25)	
Unemployed	157 (52)	16 (10)	

\*significant *p* < 0.05 based on chi-square analysis**Table 2** Sample characteristics (physiological variables) and prevalence of meeting physical activity recommendations

Sample characteristics	Total sample <i>n</i> = 305(%)	Meeting physical activity recommendations <i>n</i> = 66 (21.6%)	<i>P</i> -value
BMI (kg/m <sup>2</sup> )			0.600
Normal 18.5–24.99	34 (11)	7 (21)	
Overweight >25–29.99	118 (39)	29 (25)	
Obese >30	153 (50)	30 (20)	
Current medication			
Blood pressure lowering	217 (71)	45 (21)	0.500
Lipid lowering	189 (62)	40 (21)	0.800
Oral-hypoglycaemic drugs	260 (85)	53 (20)	0.200
Insulin	75 (25)	12 (16)	0.200
Diet control	45 (15)	32 (71)	0.200
Duration of diabetes (years)			0.500
< 5	140 (46)	37 (26)	
6 to 11	117 (38)	18 (15)	
12 to 18	33 (11)	6 (18)	
> 18	15 (5)	5 (33)	
Blood pressure (systolic/diastolic) mmHg**			0.500
Within target (<140/<80)	237 (78)	49 (21)	
High (≥140/≥80)	68 (22)	17 (25)	
HbA1c (%)**			0.300
Normal ≤7%	127 (42)	31 (24)	
High >7%	178 (58)	35 (20)	
Fasting lipid profile (mmol/L)**			
Cholesterol Within target (< 5.0)	201 (66)	44 (22)	0.900
Cholesterol High (≥5.0)	104 (34)	22 (21)	
HDL Within target (>1.0)	254 (83)	58 (23)	0.300
HDL Less protective (≤1.0)	51 (17)	8 (16)	
LDL Within target (<2.6)	188 (62)	40 (21)	0.800
LDL High (≥2.6)	117 (38)	26 (22)	
TG Within target (<1.7)	205 (67)	42 (20)	0.500
TG High (≥1.7)	100 (33)	24 (24)	
Comorbidities			0.030*
Yes	277 (91)	55 (20)	
No	28 (9)	11 (39)	

BMI body mass index, HbA1c Glycated haemoglobin, HDL high-density lipoprotein, LDL low-density lipoprotein, TG triglycerides

\*significant *p* < 0.05 based on chi-square analysis

\*\*Oman diabetes mellitus management guidelines (2015)

females with uncontrolled diabetes (61.0% vs 55.0%). Only 9.2% of the total sample were registered with no comorbidities in the clinical notes (Table 2). There was no significant difference in meeting PA recommendations across the physiological variables except for individuals reporting no-comorbidities *P* = 0.030.



### Perceptions on stages and status of physical activity

Eighty-nine percent of the sample reported that PA is important in diabetes management, however the majority (83.0%) reported pre-action stages of PA; the highest proportion considering themselves “not ready” (36.7%). More males than females reported being at an “action” or “maintenance” stage of PA (7.8% vs 2.3%, and 14.0% vs 11.0%, respectively). However, the association of gender with self-reported stages of PA was not statistically significant. Despite 80.0% of the sample reporting that they received PA advice in their respective diabetes clinics, only half of them perceived that they performed sufficient PA/wk. (49.0%) (Table 3). Meeting PA recommendations was higher in individuals reporting being at “Action” stage of PA  $P < 0.001$ , and/or reporting no barriers to PA.

Median (25th, 75th percentiles) sitting time was 705 (600, 780) min/d. Individuals meeting PA recommendation had significantly lower sitting time of 600 (540, 720) min/d than 720 (600, 840) min/d in individuals not meeting the recommendation.

### Physical activity and sitting time (GPAQ results)

Overall, one fifth (21.6%,  $n = 66$ ) of the study population met the recommended WHO PA levels of  $\geq 600$  MET-min/wk. (34.6% males vs 12.0% females). The mean (SD) and median (25th, 75th percentiles) MET-min/wk. count achieved was 680 (2347) and 0 (0, 420) min/wk. Mean

(SD) and median (25th, 75th percentiles) MET-min/wk. value for individuals meeting the recommendations was 2882 (4405) and 1680 (960, 2790) min/wk., vs 73 (145) and 0 (0, 0) MET-min/wk. for individuals not meeting them. Not meeting PA recommendations was classified as insufficient activity (MET-min/wk.  $>0$  and  $<600$ ) in 18.0% ( $n = 55$ ) of the population (28.5% males vs 10.3% females) and no activity (MET-min/wk. = 0) in 60.3% ( $n = 184$ ) of the population (36.9% males vs 77.7% females) (Fig. 1).

Just above half of the total MET-min/wk. from all three domains (207,596 MET-min) was achieved through the ‘leisure’ domain (109,496 MET-min). This was equally true for both males and females, as illustrated in Fig. 2. Compared to males, females were less physically active across the three PA domains (work, travel and leisure).

Binary regression analysis showed that the odds of meeting PA recommendations was higher in males compared to females (OR 4.8, 95% CI 2.5–9.1), in individuals  $\leq 57$  years old compared to individuals  $>57$  years old (OR 3.0, 95% CI 1.6–5.9), in individuals reporting ‘active stages’ of PA compared to those ‘not active’ or ‘getting ready’ for PA (OR 2.2, 95% CI 1.2–4.1) and in those who reported no barriers to performing PA compared to those who reported barriers (OR 2.7, 95% CI 1.4–4.9) (Table 4).

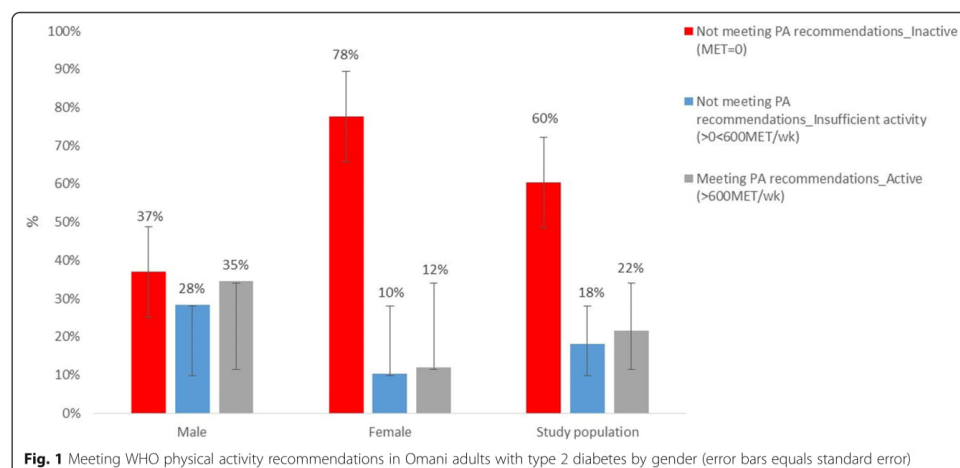
Looking at domain specific correlates of meeting PA recommendations, for the work domain, meeting recommendations was more likely in those reporting they were

**Table 3** Sample characteristics (perceptions on stages and status of PA) and prevalence of meeting physical activity recommendations

Sample characteristics	Total sample $n = 305$ (%)	Meeting physical activity recommendations $n = 66$ (21.6%)	Not Meeting physical activity recommendations $n = 239$ (76.4%)	$P$ -value
Self-reported stages of change in physical activity				$<0.001^*$
Not ready (Pre-contemplation)	112 (37)	8 (7)	104 (93)	
Getting ready (contemplation)	95 (31)	24 (25)	71 (75)	
Preparation	46 (15)	14 (30)	32 (70)	
Action	14 (5)	7 (50)	7 (50)	
Maintenance	38 (12)	13 (34)	25 (66)	
PA advice				0.200
Yes	245 (80)	49 (20)	196 (80)	
No	60 (20)	17 (28)	43 (72)	
Reporting performing sufficient PA/wk				0.050
Yes	150 (49)	39 (26)	111 (74)	
No	155 (51)	27 (17)	128 (83)	
Reporting barriers to performing PA				$<0.001^*$
Yes	177 (58)	24 (14)	153 (87)	
No	128 (42)	42 (33)	86 (67)	
Mean sitting time (SD) min/d	688.1 (143.5)	637.4 (141.2)	702.0 (141.3)	$<0.001^{**}$
Median sitting time (25th, 75th percentiles) min/d	705 (600, 780)	600 (540, 720)	720 (600, 840)	

\*significant  $p < 0.05$  based on chi-square analysis

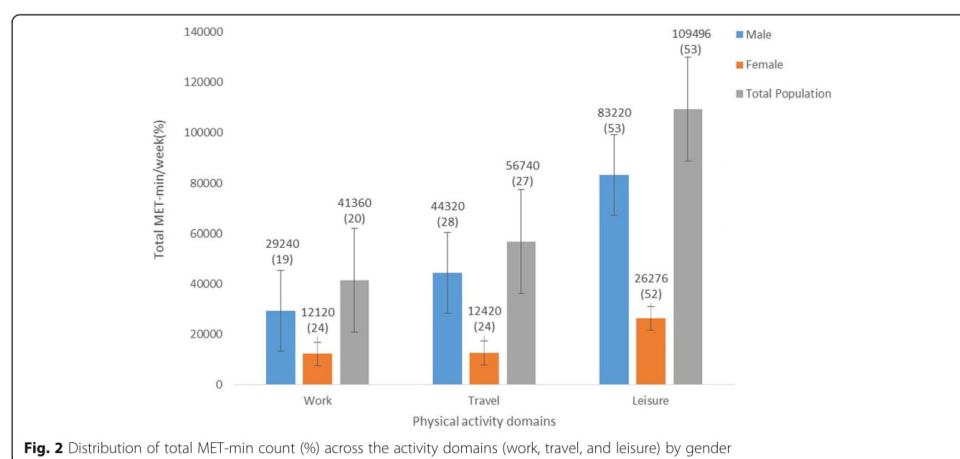
\*\*non parametric test (Mann-Whitney U test)



in 'active stages' of PA (OR 4.8, 95% CI 1.4–15.8) and reporting no barriers to PA (OR 4.4, 95% CI 1.2–16.5). Males (OR 9.2, 95% CI 3.2–5.9), individuals  $\leq 57$  years (OR 3.1, 95% CI 1.3–7.6) and reporting no barriers to PA (OR 2.5, 95% CI 1.1–5.8) were more likely to meet PA recommendations in travel domain. Males, individuals  $\leq 57$  years and those reporting active stages of PA were more likely to meet PA recommendation in the leisure domain (OR 3.1, 95% CI 1.4–6.6, OR 3.1, 95% CI 1.4–7.1 and OR 5.5, 95% CI 2.5–12.0, respectively) (explanatory table is attached in the Additional file 1).

#### Correlates of sitting time

Sitting time ranged from 240 to 890 min/d (4–15 h). Females reported longer sitting time than males. Median (25th, 75th percentiles) sitting time in females was 720 (600, 780) min/d vs 660 (600, 840) min/d in males. However, gender was not significantly associated with prolonged sitting  $P > 0.050$ . Age on the other hand, was the only significant correlate for longer sitting time. Older individuals ( $> 57$  years) had significantly longer sitting time compared to individuals  $\leq 57$  years (OR 2.8, 95% CI 1.7–4.6).



**Table 4** Correlates of meeting WHO PA recommendations in adults with type 2 diabetes

Parameter n = 305 (%)	Meeting physical activity recommendations (%)	Not meeting physical activity recommendations (%)	OR	95% CI	Sig
Gender:					
Males = 130 (42.6%)	45 (35)	85 (65)	4.8	2.5–9.1	<0.001
Females = 175 (57.4%)	21 (12)	154 (88)	Ref	.	.
Age:					
≤ 57 = 155 (50.8)	45 (29)	110 (71)	3.0	1.6–5.9	0.001
> 57 = 150 (49.2)	21 (14)	129 (86)	Ref	.	.
Self-reported stages of PA					
Not/getting ready (inactive) = 207 (67.9)	32 (15)	175 (85)	2.2	1.2–4.1	0.009
Preparation/action/maintenance (active) = 98 (32.1)	34 (35)	64 (65)	Ref	.	.
Reporting barriers to performing PA					
No Barriers = 128 (42)	42 (33)	86 (67)	2.7	1.4–4.9	0.002
Reported Barriers = 177 (58)	24 (14)	153 (86)	Ref	.	.

**Preferences for PA and intervention delivery components**

When participants were asked to select their preferred PA for which they would like to get support, walking was of interest to 97.4% of the study population. Just over a third of the sample (38.0%) were interested in PA consultations/clinics integrated in routine diabetes care in primary care setting followed by structured PA exercises (13.0%) and PA referrals (6.0%). Whilst 27.0% suggested mixed PA components including consultations/clinics, structured exercises, and referrals to PA facilities, other participant, reported “Don’t know” and “no preferred PA component” (12.0% and 4.0% respectively).

Less than half of the sample participants reported they “did not know” who should be responsible for PA in diabetes care (42.0%). The diabetes doctor was selected by a fifth of the population (22.0%) followed by the dietician (9.0%), and 27.0% reported various other healthcare professional namely physiotherapists, PA experts, diabetes nurse and health educator.

**Discussion**

The aim of this study was to estimate levels of PA, sitting time and the factors associated with meeting PA recommendations and prolonged sitting time in adults with T2D in Oman. The work reported contributes to limited literature on PA internationally and in particular PA patterns in diabetes care in the GCC.

Worth mentioning, the response rate in this study was high possibly due to collecting data within clinical settings where participants felt comfortable to participate in the study during their waiting time for their routine diabetes clinics.

Evidence on activity levels in populations with T2D is variable across countries. However, low levels of PA in T2D populations have been reported in several studies [15] including those from Arabic speaking countries [16, 22, 23].

Whilst meeting PA recommendations in this study is higher than national levels (15%), activity levels in the current study are much lower than those reported in populations with T2D in the UK (34%) [24] and USA (36 to 50%) [25]. Of greatest concern is the fact that more than half (60.3%) of this study sample, compared to 55% in similar studies, reported no activity (MET = 0) [26], indicating significant inactivity levels. Despite the differences in PA study tools that may contribute to disparities in PA levels across studies, the inactivity levels in this study population is disappointing in view of the consistent evidence on the physiological, metabolic and haemodynamic benefits of PA in the management of T2D [27].

Males, younger age (<57 years), reporting being at “active stages” of PA and reporting “no barriers” to performing PA were significant positive factors associated with meeting PA recommendations in this study sample. The global trend of male dominance in meeting PA recommendation was prominent in the travel domain followed by the leisure domain. Higher travel activity levels in males could be due to cultural and religious factors in Arabic and Muslim countries. Congregational prayers in mosques are considered to have more social and spiritual benefit than praying by oneself. Males value being able to walk to and from the mosques five times every day for their daily prayers especially given that every neighbourhood has access to mosques [28]. Females, who are more likely to be obese [29], prefer to pray and stay at home for child care reasons. This may additionally be augmented by a lack of gender specific facilities and safe places for females to perform PA activity as reported in neighbour countries namely UAE and Saudi Arabia [30–32]. Hence gender segregated PA promotional interventions for adults with T2D should target females who are more vulnerable to inactive behaviour and uncontrolled diabetes. On the contrary, a study in

Lebanon reported that females were more active in both the general population, as well as the population with T2D [16]. The difference in gender effect might be attributed to PA supportive cultural, educational, environmental and economic status specific to Lebanon that requires further exploration to learn lessons on effective PA interventions for females that could possibly be tested in Oman.

Despite the higher absolute leisure activity in males compared to females, the relative amounts of leisure activity contributed the most to the overall activity levels, in both males and to females. Leisure time PA has been reported to be significantly associated with reduced mortality risks (20% to >37%) and favourable cardiovascular outcomes [33]. No clear association or even an inverse relationship is observed for work or travel PA [34]. In general, individuals who had not met PA recommendations in this study had higher blood pressure, HbA1c, lipid profile, and more comorbidities. Hence, PA promotional interventions should consider opportunities within activity domains: work, travel and most importantly leisure for sub-populations with T2D across the various cultures. Meeting PA recommendations in travel and leisure domains was also seen to be more likely in younger individuals. Younger individuals in the current study have less comorbidities and hence may experience less discomfort compared to older aged individuals with T2D who might be concerned about their disease condition [15].

In the current study, self-reported PA stages of change namely “pre-contemplation” and “contemplation” was associated with low activity levels specifically in work and leisure domains. The fact that more than half of the study population were at in-active stages of PA raises concerns in view of the current diabetes care in Oman that specifies the provision of advice on PA [21]. This is a critical finding as the majority (80.0%) of the study population indicated that they received PA advice, but this was not associated with being physically active or meeting PA recommendations. The current PA advice practiced in routine diabetes care should include behaviour change techniques to ensure stage progression for individuals with T2D from pre-action to action and maintenance stages of change. In a recent study, five behaviour change techniques, namely prompt focus on past success, barrier identification/problem-solving, use of follow-up prompts, provide information on where and when to perform the behaviour and prompt review of behavioural goals of PA were significantly associated with increased PA behaviour in T2D and improving HbA1c [35]. Practicing PA barrier identification across activity domains is important as responding “yes” to barriers to performing PA in the current study was apparent in those not meeting the PA recommendations specifically in work and travel activity domains. Hence,

opportunities for culturally suitable active workplaces and transportation should be identified and considered.

Despite using the same measurement tool, the average sitting time in this study population with T2D was almost six times higher than what has been reported locally in the Sur general population of 120 min/d [11]. This disparity could be attributed to differences characteristics and disease condition of the studied population. Similarly, the average sitting time in the current study was more than double the time in adults with T2D in Canada of 278 min/d [14], however different measuring tool was used. Given the evidence on the increased risk of cardio-vascular mortality with long sitting time on health [36], PA interventions should emphasise shorter and interrupted sitting time especially for vulnerable sub-groups with T2D. However, further research for the population with T2D on domain-specific sedentary behaviours is necessary to plan for appropriate public health interventions targeting more PA and less sedentary behaviour.

The only correlates for longer sitting time in this population study was older age (>57 years). This finding corresponds to a study in the USA that reported increase in sedentary time with age for both men and women in the general population [37]. However, gender stratified significant correlates of longer sitting time in the study in Sur were younger age, employed individuals, higher BMI (in females) and higher education (in males). However, lack of significant associations of long sitting time with any other socio-economical or clinical variables in populations with T2D was evident in a study in Canada where only being a non-immigrant, and having a university degree were the factors associated with more min/d spent sitting [38]. Variations in significant correlates can be attributed to differences in definitions of sedentary behaviour including insufficient PA, and sitting time and differences in measurement tools [39].

Similar to a study in Scotland in adults with T2D [24], walking was the preferred activity over running, cycling, swimming and other activities indicated by this population. Walking interventions combined with pedometers as motivational tools are more likely to improve PA behaviour in the general population and adults with T2D [40, 41]. Hence, irrespective of culture, walking can be considered as an appropriate method of PA promotion for adults with T2D as they are sedentary individuals and aware of their need for lifestyle change.

In the current study population, just over a third were interested in PA consultations in routine diabetes care. In terms of who participants felt they would prefer to be responsible in delivering PA services within diabetes care, 40% selected “don’t know” while only a fifth (22%) preferred diabetes doctors. The fact that participants were unsure on the health worker for PA promotion

opens an opportunity to utilize other “non-doctors” health care providers to endorse PA within diabetes care. Effectiveness of PA consultations linked to behaviour change techniques in increasing PA behaviour in population with diabetes has been consistent in several reviews and randomized control trials carried out in the UK, Canada, USA and Belgium [35, 42]. This approach is yet to be investigated in the Arab world.

The findings of the current study are considered in light of several limitations. Due to the cross-sectional nature of the study, the associations reported may not indicate causality. One must acknowledge potential errors associated with self-reported measures of PA and sitting time. The subjective nature of PA self-reporting measurement tools used across studies may have contributed to discrepancies in PA recordings especially when PA definitions (moderate and vigorous) are explained differently. In general self-reporting PA measurement tools do not provide accurate estimates (limited validity and reliability) especially across distinct demographic, cultural groups [43]. Moreover, PA questionnaires, namely GPAQ in this study, are less sensitive to quantifying mild daily activities that are reported to be the major activity in older and sub-populations [44]. Validating GPAQ for this population using an objective measure may be useful for quantifying activity levels and ultimately effective PA promotional interventions.

## Conclusions

Overall, levels of PA were low across all activity domains and median sitting time was high. Females, older age, reporting ‘in-active stages’ of PA and barriers to PA were negatively correlated with meeting PA recommendations. Given the significant association of meeting PA recommendations with gender, interventions to modify PA behaviours should be linked to gender-specific barriers to PA. Sitting time in older individuals with T2D was greater than regional and global estimates. PA consultations based on behaviour change techniques and which are specific to individual PA stages of change may be promising strategies to increasing PA behaviour and reduce sitting time.

## Additional file

**Additional file 1:** Table correlates of physical activity across domains. (PDF 128 kb)

## Abbreviations

BMI: Body mass index; CI: Confidence interval; GCC: Gulf Cooperation Council; GPAQ: Global physical activity questionnaire; HDL: High density lipoproteins; LDL: low density lipoproteins; OR: odds ratio; PA: Physical activity; SD: Standard deviation; SE: Standard error; T2D: Type 2 diabetes; TG: Triglycerides; WHO: World Health Organization

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## Availability of data and materials

The datasets generated or analysed during the current study are not publicly available due to limitations on utilizing patient's health records owned by the ministry of Health. However it is available from the corresponding author on reasonable request and approvals from Oman Ministry of Health.

## Authors' contributions

TS collected, analysed and interpreted the data and wrote the manuscript; SA interpreted the data and reviewed the manuscript; YA, AC, EB, and AA supervised, reviewed the study proposal and manuscript. All authors read and approved the final manuscript.

## Ethics approval and consent to participate

Ethical approval was obtained from the Regional Research Committee in Muscat, Oman Ministry of Health. All eligible participants provided informed consent prior to data collection.

## Consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

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## Appendix 4.2: Published study (2) Perceived barriers to leisure time physical activity in adults with type 2 diabetes attending primary health care in Oman

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### Research

## BMJ Open Perceived barriers to leisure time physical activity in adults with type 2 diabetes attending primary healthcare in Oman: a cross-sectional survey

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### ABSTRACT

**Objectives** Physical activity is fundamental in diabetes management for good metabolic control. This study aimed to identify barriers to performing leisure time physical activity and explore differences based on gender, age, marital status, employment, education, income and perceived stages of change in physical activity in adults with type 2 diabetes in Oman.

**Design** Cross-sectional study using an Arabic version of the 'Barriers to Being Active' 27-item questionnaire.

**Setting** Seventeen primary health centres randomly selected in Muscat.

**Participants** Individuals >18 years with type 2 diabetes, attending diabetes clinic for >2 years and with no contraindications to performing physical activity.

**Primary and secondary outcome measures** Participants were asked to rate how far different factors influenced their physical activity under the following categories: fear of injury, lack of time, social support, energy, willpower, skills, resources, religion and environment. On a scale of 0–9, barriers were considered important if scored ≥5.

**Results** A total of 305 questionnaires were collected. Most (96%) reported at least one barrier to performing leisure time physical activity. Lack of willpower (44.4%), lack of resources (30.5%) and lack of social support (29.2%) were the most frequently reported barriers. Using  $\chi^2$  test, lack of willpower was significantly different in individuals with low versus high income (54.2%vs40%,  $P=0.002$ ) and in those reporting inactive versus active stages of change for physical activity (50.7%vs34.7%,  $P=0.029$ ), lack of resources was significantly different in those with low versus high income (40%vs24.3%,  $P=0.004$ ) and married versus unmarried (33.8%vs18.5%,  $P=0.018$ ). Lack of social support was significant in females versus males (35.4%vs20.8%,  $P=0.005$ ).

**Conclusions** The findings can inform the design on physical activity intervention studies by testing the impact of strategies which incorporate ways to address reported barriers including approaches that enhance self-efficacy and social support.

### INTRODUCTION

Oman is located in Southwest Asia on the Southeast coast of the Arabian Peninsula. Similar to its neighbouring countries (United

### Strengths and limitations of this study

- Barriers to performing leisure physical activity for adults with type 2 diabetes were investigated in Oman, where prevalence of both diabetes and physical inactivity is high.
- Questions on possible barriers to performing physical activity linked to religion and environment were included.
- The tool used in this study was an English to Arabic language translated questionnaire that may have affected the validity of questions.

Arab Emirates, Saudi Arabia, Qatar, Bahrain and Kuwait), Oman has witnessed enormous economic advancement in recent decades, along with significant increases in non-communicable diseases including a rising prevalence of diabetes. Diabetes prevalence in Oman has increased from 8.3% in 1991 to 12.3% in 2008, and recent estimates are in the order of 14.8%, exceeding global rates.<sup>1,2</sup> WHO has indicated that physical inactivity is one of the top 10 leading global causes of mortality and disability worldwide, and the principal cause for approximately 27% of diabetes and approximately 30% of ischaemic heart disease.<sup>3</sup> In Oman, it has been reported that almost 70% of the population are physically inactive (daily activity of ≤10 min).<sup>4</sup> This raises concerns regarding the impact these high levels of physical inactivity may be having on lifestyle-related chronic diseases including diabetes on healthcare expenditures and overall population health.<sup>5</sup>

The protective effects of physical activity (PA) in the management of diabetes, specifically type 2 diabetes (T2D), have been widely reported.<sup>6,7</sup> WHO recommends at least 150 min of moderate to vigorous PA or 75 min of vigorous PA/week.<sup>8</sup> However, >60% of patients with diabetes in Western



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countries do not meet the recommended levels of PA.<sup>9 10</sup> The Oman World Health Survey (OWHS) 2008 reported that in Oman only 15% of patients with diabetes (98% of them with T2D) met PA recommendations using the Global Physical Activity Questionnaire (GPAQ).<sup>2</sup>

The importance of leisure time PA in meeting PA recommendations is consistently<sup>11</sup> associated with reduced mortality risks (20% to >37% risk reduction) and favourable cardiovascular outcomes.<sup>12</sup> This relationship appears to have a dose-response effect where the upper threshold for mortality benefit occurs at three to five times the leisure PA recommendations of 7.5 to <15 MET hours/week.<sup>12</sup> No clear association is observed for occupational or travel PA.<sup>13</sup>

Theoretical models underpinning effective interventions to promote personalised PA (contents, methods and approaches) should focus on benefits and ways to overcome barriers to PA.<sup>14</sup> Literature to date mainly from Western countries has reported a number of potential barriers to performing PA in adults with diabetes. These include lack of time,<sup>15–18</sup> physical constraints including pain,<sup>19</sup> lack of knowledge and limited facilities.<sup>20</sup> Differences in reporting barriers to PA have been noted across genders, age groups, environments, cultures and disease status. Female gender, increasing age, unsafe neighbourhoods, being overweight and being a smoker increased the odds of reporting barriers to PA among migrant populations like African-Americans, South Asian British and Mexican Americans.<sup>21–23</sup> In the Arab countries, modest evidence on barriers to PA in both the general population and in adults with T2D suggests that lack of time, coexisting diseases and adverse weather conditions<sup>14 24–29</sup> are the main factors. Moreover, the climate in this region may be a drawback to meeting recommended levels of PA due to high temperatures during the day, particularly in the sandy/desert areas. During the summer months, these countries including Oman experience major heat waves (>40° C) and humidity levels that could reach 90%.

The current study aimed to identify barriers to performing leisure time PA in adults with T2D in Oman and the distribution of barrier scores across different socio-demographic characteristics and perceived stages of change in PA.

## METHODS

### Study design, setting and participants

This cross-sectional interview-based study was part of a larger study that examined correlates of PA and sitting time in adults with T2D, and barriers to leisure PA in the same population. Results regarding the PA patterns of the population using the GPAQ are reported elsewhere.<sup>30</sup> This current paper identified barriers to performing leisure PA expressed by Omani adults with T2D using adapted questions from the Centers for Disease Control and Prevention (CDC) questionnaire<sup>31</sup> conducted in April/May 2015 in Muscat (urban communities). Reporting of

this study follows the guidelines for strengthening the reporting of observational studies in epidemiology.<sup>32</sup>

All patients with T2D attending their routine diabetes clinics in 17 randomly selected primary healthcare centres in Muscat were approached to take part in the study. Inclusion criteria were age >18 years and being followed up in a diabetes clinic for >2 years and ability to provide informed consent. For illiterate participants, informed consents were taken from their spouse, son, daughter or other close family member. Participants with type 1 diabetes, newly diagnosed (<6 months) or who had difficulty in performing any PA, including history of myocardial infarction of <6 months and multiple organ failure, were excluded.

### Data sources/measurement

In addition to recording physiological data (body mass index (BMI), medication, duration of diabetes, blood pressure (BP), lipid profile and comorbidities coinciding with diabetes) from the electronic health system, a multi-section questionnaire with a range of answers in closed format was administered by a trained interviewer. The following information was collected.

### Socio-demographic data

Included gender, age, marital status, education, household income and employment.

### Perceptions on stage of change in PA

Based on the trans-theoretical theory of behaviour change,<sup>33</sup> subjects were asked to identify their perceived stage of change in PA. Participants were to select 'maintenance stage' if they were participating in moderate PA five or more times per week or in vigorous activity three to five times per week longer than six consecutive months or select 'action stage' if <6 months. 'Preparation stage' was selected by subjects who were thinking about starting exercise such as walking in the near future or doing vigorous activity less than three times per week or moderate activity less than five times per week. Contemplation stage 'getting ready' was selected by subjects who were thinking about starting exercise or walk in the next six months. Subjects who were not thinking about starting any PA in the near future selected precontemplation stage 'not ready'.

### CDC questionnaire on barriers to leisure PA

An English to Arabic-translated CDC questionnaire 'Barriers to Being Active' was used in a study in Saudi Arabia<sup>14</sup> with 21 questions on seven barriers (lack of time, lack of social support, lack of energy, lack of will-power, fear of injury, lack of skill and lack of resources). Permission to use the questionnaire was obtained from the lead author on 24 November 2014 (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2813614/figure/F0001/>). However, in that tool no statements on religion or environment as possible barriers to PA were included. To address this gap and to formulate robust items on these topics, we undertook several procedures. Literature



search was conducted to identify possible content for the new items from similar studies in neighbour countries with similar socio-economical characteristics.<sup>28 29</sup> Potential religious barriers considered questions on religious beliefs restricting PA, accepted clothing for PA and religious perceptions on PA.<sup>14 25 26</sup> Potential environmental barriers included questions on extreme weather conditions, PA in summer time and availability of appropriate environment for PA.<sup>16 25</sup> Content and face validity of the questionnaire were assessed by our investigatory team and draft questions were then discussed with a sample of patients prior to field testing and adjustments were made to ease comprehension and ensure translation to Arabic was appropriate.

A set of three related questions (total of 27 questions) presented in random order within the questionnaire represented one barrier category. A scoring system<sup>31</sup> was used to indicate how likely each statement/item was considered to be a barrier (very likely=3, somewhat likely=2, somewhat unlikely=1, very unlikely=0). Scores of the three theme-related questions were added up to provide a total for each category of barriers. Possible scores for each barrier category ranged from 0 to 9. A score of  $\geq 5$  was considered as an important barrier to overcome.<sup>31</sup> A copy of the used (Arabic and English) questionnaire can be found in online supplementary materials 1 and 2.

To ensure common understanding and acceptability, an interview recording was undertaken in Muscat in 25 randomly selected adult with T2D (population of interest) outside the sampled health centres of the study. Results were discussed and reviewed by the investigation team and an independent statistician.

Based on the data from the current study, the scale quality (27-item study questionnaire) including internal consistency reliability measures was investigated through the use of factor analysis using SPSS V:22 and supported by McDonald's coefficient omega using the free and open source R.<sup>34 35</sup>

### Study size

Power analysis was performed to estimate the prevalence of meeting PA recommendations in adult population with T2D in a parallel study conducted in the same population.<sup>30</sup> We assumed that meeting PA recommendation is at least in part facilitated by reporting fewer barriers to PA<sup>36</sup> and used an estimated 15% prevalence of adequate PA in patients with diabetes, as reported in the 2008 OWHS.<sup>37</sup> Using 95% confidence limits, a response rate of 80%, a precision of  $\pm 4\%$  and smallest expected frequency of 15%, the calculated sample size was  $\sim 300$  participants across primary health centres in Muscat region, the capital of Oman.

### Training

A multidisciplinary team of two nurses, one senior dietitian, one medical orderly and two doctors were recruited for data collection. A 1-day training on administration

of the questionnaire was delivered by the national focal point on PA in Oman Ministry of Health. Data entry, cross-checking and cleaning were done through Epi Info 7 by an independent personnel. Entered data were transferred to SPSS V:22 for analysis and subsequent results.

### Statistical methods

Descriptive statistics were expressed as percentages and mean (SD), median (quartiles) to describe the study sample characteristics. Sum of scores from the three related questions per category (range from 0 to 9) were expressed as median, lower quartile (LQ), and upper quartile (UQ). Correlations between the sum of scores of the nine barrier categories were tested. Furthermore, data were dichotomised to scores  $< 5$  and  $\geq 5$  to determine the highly reported barriers as advised in the CDC questionnaire and practised in a study in Saudi Arabia.<sup>31</sup>  $\chi^2$  analysis was carried out to identify the distribution of the high barrier scores ( $\geq 5$ ) across the independent socio-demographic factors including gender (male vs female); age (to ensure sufficient power and adequate numbers for further statistical analysis the population was divided by the mean age  $\leq 57$  vs  $> 57$  years); marital status (currently unmarried vs married); education (those unable to read or write ('uneducated') versus those having attended primary school or beyond ('educated')); household income ( $< 500$  vs  $\geq 500$  Omani rials ('OR')); and employment (unemployed, including those retired vs employed). Self-reported stage of change in PA was expressed as one of two categories: inactive if reporting 'precontemplation' or 'contemplation' and potentially active if reporting being at 'preparation', 'action' or 'maintenance' stages of PA. Corrected P values (Yate's continuity) were reported for high barrier scores against the studied independent variables.

Principal components analysis (PCA) was performed to identify composite scores for the components underlying the items/questions in the study scale. A nine-factor solution was used to investigate the contributions of the 27-item/questions to the nine barrier categories.<sup>38</sup> Furthermore, factor loading matrix was examined using Oblimin rotation<sup>39</sup> where correlations between the extracted components were obtained.

## RESULTS

### Socio-demographic

Out of 312 patients approached, 305 (98%) completed the questionnaire. Slightly more females were represented in this sample (57.4%) than males. The population was slightly older with mean (SD) age of 57 (10.8) years. Additionally, more than two-thirds being married (78.8%) and just about half unable to read or write (48.9%). More than a third of the study population (39.3%) reported household income of  $< 500$  OR (less than national average)<sup>40</sup> and the majority (77%) reported unemployment (including retirement). More males than



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females were educated (70% vs 37%) and employed (45% vs 7%) (table 1).

### Physiological status

Median (LQ, UQ) duration of diabetes in this population was 6.0 (4.0, 10.0) years. The majority of the participants had hypertension (n=217, 71%) or/and hyperlipidaemia (n=189, 62%) coinciding with their diabetes. All of them were using antihypertensive or/and lipid-lowering medications as appropriate. More than three-quarters of those taking antihypertensives (78%) and two-thirds of those using lipid-lowering drugs (66%) had BP readings and fasting serum cholesterol within target levels (BP <140/80 mm Hg and fasting serum cholesterol of <5 mmol/L).<sup>41</sup> Fifteen per cent (n=45) were controlling their diabetes by diet alone versus 85% (n=260) on oral anti-hypoglycaemic medications, in which 25% (n=75) were additionally on insulin. Mean (SD) BMI was 31.0 (6.0) kg/m<sup>2</sup> where 89% (n=271) had BMI >25 kg/m<sup>2</sup> in which 50% (n=153) were obese (BMI >30 kg/m<sup>2</sup>) and 39% (n=118) were overweight (BMI >25–29.99 kg/m<sup>2</sup>). Glycated haemoglobin HbA1c was >7% (>48 mmol/mol) in more than half of the population (58%), indicating poor diabetes control (table 1).

### Self-reported stages of PA

Only 17% (n=52) of participants considered themselves actively participating in regular, moderate or vigorous PA (22% of males vs 13% of females). Of the remainder, the majority reported being 'not ready' (37%), 'getting ready' (31%) or in 'preparation' (15%) (table 1).

### CDC questionnaire on barriers to leisure PA

For the 27-item/question scale, McDonald's coefficient omega was =0.750, indicating moderate reliability of the scale.<sup>38</sup> Further, PCA analysis with nine-component solution generally supported the previously found subscales (three questions per barrier category) in barriers to performing PA mainly components 2, 4, 5, 6 and 9 representing fear from injury, environmental barriers, religious barriers, lack of willpower and lack of resources respectively (see online supplementary material 3). However, cross-contributions were evident in four out of the nine extracted components, namely component 1 (lack of willpower, time, energy and skills), component 3 (lack of time and energy), component 7 (lack of social support and skills) and component 8 (lack of social support and energy).

Each of the subscales for the nine studied barriers had good reliability (McDonald's coefficient omega was =0.900). Based on this, further results are presented using sum scores.

The majority of the population, 97.7% (n=298), reported at least one barrier to performing leisure PA median (LQ, UQ) was 6 (4, 7). Population distributions were not normal across all reported barrier categories. Median sum scores were all <5 as illustrated in figure 1. Except for reporting lack of willpower and lack of

**Table 1** Selected participants characteristics

Population characteristics	Total population n=305 (100%)
<b>Gender</b>	
Male	130 (42.6)
Female	175 (57.4)
<b>Age (years)</b>	
≤57	155 (51)
>57	150 (49)
<b>Marital status</b>	
Currently unmarried	65 (21)
Currently married	240 (79)
<b>Education</b>	
Not educated	149 (49)
Educated	156 (51)
<b>Income</b>	
<500 OR	120 (39)
≥500 OR	185 (61)
<b>Employment</b>	
Not employed	234 (77)
Employed	71 (23)
<b>Physiological</b>	
Duration of diabetes (years)	Median (LQ, UQ) 6 (4, 10)
<b>Self-reported comorbidities*</b>	
Yes	277 (91)
No	28 (9)
<b>Current medication</b>	
Antihypertension	217 (71)
Lipid-lowering drugs	189 (62)
Oral-hypoglycaemic drugs	260 (85)
Oral-hypoglycaemic drugs with insulin	75 (25)
Diet control	45 (15)
<b>Blood pressure†</b>	
Within target (<140/<80)	237 (78)
High (≥140/≥80)	68 (22)
<b>Fasting lipid profile (mmol/L)†</b>	
Cholesterol within target (<5.0)	201 (66)
Cholesterol high (≥5.0)	104 (34)
<b>Body mass index (kg/m<sup>2</sup>)†</b>	
Healthy weight range (18.5–24.99)	34 (11)
Overweight (>25–29.99)	118 (39)
Obese (>30)	153 (50)
<b>HbA1c (%)† (&gt;48 mmol/mol)</b>	
Normal≤7	127 (42)
High>7	178 (58)

Continued



Table 1 Continued

Population characteristics	Total population n=305 (100%)
Self-reported stages of physical activity	
Not ready (precontemplation)	112 (37)
Getting ready (contemplation)	95 (31)
Preparation	46 (15)
Action	14 (5)
Maintenance	38 (12)

\*Reported hypertension, hyperlipidaemia, thyroid dysfunction or any other chronic condition coinciding with diabetes.

†Oman diabetes mellitus management guidelines (2015).<sup>41</sup>

LQ, lower quartile; OR, Oman rial; UQ, upper quartile.

resources, 75% of sum scores of other reported barriers were  $\leq 5$ .

Categorising barrier scores to  $<5$  and  $\geq 5$  (significant barrier) highlighted that 'lack of willpower' (n=139), 'lack of resources' (n=93) and 'lack of social support' (n=89) were the most frequently reported 'significant barriers' to PA (figure 2). Barriers found to be significant in both males and females were lack of willpower (41.5% males: 48.6% females) and lack of resources (32.3% males: 29.1% females). In addition, lack of time in males (26.9%) and lack of social support in females (35.4%) were also noteworthy (table 2).

Correlations between the sum scores of the nine studied barriers were generally weak ( $R < 0.200$ ). Positive and significant correlations of  $>0.300$  were noted among lack of energy with lack of time; lack of skill with lack of social support; lack of energy and lack of willpower; lack of skills with lack of willpower; and fear of injury with lack of skills (table 2). Interestingly, no significant correlations were seen within the religious and environmental barriers except for one weak significant positive correlation between lack of resources and environmental barriers.

Distributions of significant high barrier score ( $\geq 5$ ) across the studied socio-demographic factors and self-reported stages of change in PA differed among the nine barrier categories: 'lack of time' was frequently highly scored by males, younger adults and those who were married, employed or educated. Additionally, 'lack of social support' was highly scored by females and 'lack of energy' by employed or educated adults. However, 'lack of willpower' was highly scored by individuals with lower income or at inactive stages of PA. Moreover, 'fear of injury' was highly scored by older adults, unemployed, uneducated or individuals reporting inactive stages of PA. Furthermore, 'lack of skills' was highly scored by females, younger adults and unemployed or uneducated. 'Lack of resources', on the other hand, was frequently highly scored by married adults or with lower income. It is notable that the religious and environmental barriers had no significant different distributions across any of the studied factors (table 3).

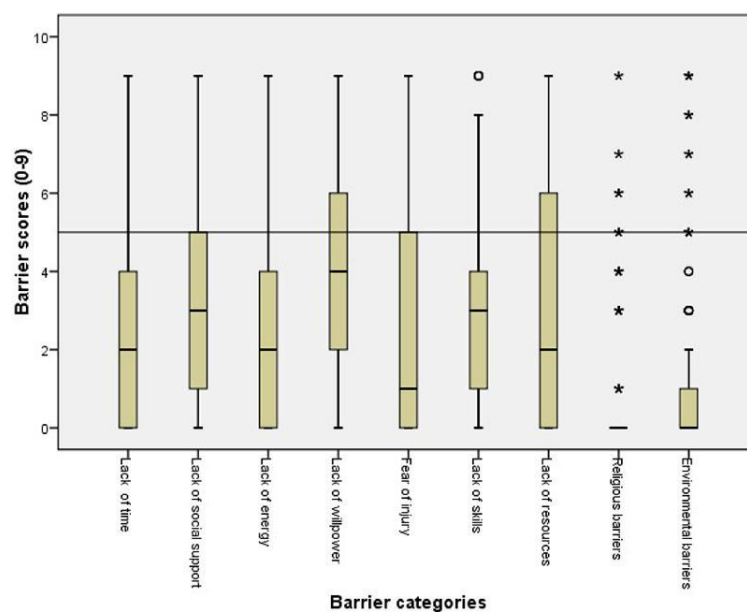


Figure 1 Box and whisker plots for the reported barrier sum scores of 0–9 (high scores defined as  $\geq 5$ ).

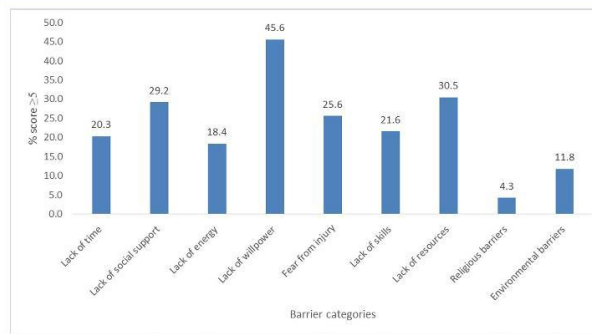


Figure 2 Percentage of reported high barrier scores ( $\geq 5$ ).

## DISCUSSION

Despite evidence on the effectiveness of meeting PA levels in the management of T2D and associated cardiovascular risk factors,<sup>6,7</sup> PA is poorly addressed in routine diabetes care.<sup>42</sup> Low PA levels in populations with T2D are consistently reported in Western countries, for example, the USA<sup>43</sup> as well as in Arabic-speaking countries, namely Oman, Saudi Arabia and Lebanon.<sup>2,44,45</sup> Addressing perceived barriers to performing recommended PA levels in this population is crucial for planning effective PA-promoting interventions.

Within a series of formative studies to inform a culturally congruent PA intervention in diabetes care,<sup>46</sup> this study has looked at perceived barriers to performing leisure time PA in an adult population with T2D attending primary care using an adapted CDC questionnaire translated to Arabic language.<sup>14</sup>

The current findings relating to willpower, resources and social support were also reported as the top three barriers to PA in the Saudi population attending primary care by AlQuaiz.<sup>14</sup> In the West, the USA in particular, the

strongest reported barriers to PA among adults with T2D were pain (41%), followed by lack of willpower (27%) and poor health (21%).<sup>47</sup>

In the current study, lack of willpower was significantly highly reported by individuals from low-income households. This finding is similar to a Canadian study which reported a negative association between financial position and on intention to participate in leisure time PA in adult population with T2D in Canada.<sup>48</sup> Additionally in a study in the USA, older individuals with low income who were found to be depressed had low participation in social activities and less odds of engaging in PA.<sup>49</sup> Nonetheless, more evidence is needed to explain how income alters the willpower for performing leisure PA in Arabic-speaking countries, namely Oman. Comparably, lack of willpower was more likely to be reported by individuals at inactive stages of PA (precontemplation or contemplation stages of PA) than those in active stages. Progressive stages of behavioural change according to the trans-theoretical model were direct correlates to PA in a review article by Trost<sup>50</sup> and direct determinants in another

Table 2 Correlations between sum scores of barrier categories

	Lack of time	Lack of social support	Lack of energy	Lack of willpower	Fear of injury	Lack of skill	Lack of resources	Religious barriers	Environmental barriers
Lack of time	1.000	0.134*	0.464*	0.118*	-0.116*	0.035	0.013	-0.092	0.013
Lack of social support	0.134*	1.000	0.125*	0.288*	0.262*	0.430*	0.083	0.011	0.039
Lack of energy	0.464*	0.125*	1.000	0.306*	-0.013	0.178*	0.171*	-0.070	0.099
Lack of willpower	0.118*	0.288*	0.306*	1.000	0.058	0.497*	0.260*	-0.112	0.053
Fear of injury	-0.116*	0.262*	-0.013	0.058	1.000	0.338*	-0.218*	0.032	-0.090
Lack of skill	0.035	0.430*	0.178*	0.497*	0.338*	1.000	0.182*	-0.052	0.005
Lack of resources	0.013	0.083	0.171*	.260*	-0.218*	0.182*	1.000	0.038	0.281*
Religious barriers	-0.092	0.011	-0.070	-0.112	0.032	-0.052	0.038	1.000	0.007
Environmental barriers	0.013	0.039	0.099	0.053	-0.090	0.005	0.281*	0.007	1.000

\*P value<0.050.





**Table 3** Distribution of high barrier scores ( $\geq 5$ ) to leisure physical activity in adult population with type 2 diabetes across socio-demographic variables and self-reported stages of change in physical activity (n=305)

(%) Scores $\geq 5$	Lack of time	Lack of social support	Lack of energy	Lack of willpower	Fear of injury	Lack of skills	Lack of resources	Religious barriers	Environmental barriers
<b>Gender</b>									
Male	26.6	20.8	21.5	41.5	24.6	13.1	32.3	3.8	10.0
Female	15.4	35.4	16.0	48.6	26.3	28.0	29.1	4.6	13.1
Corrected $\chi^2$	5.4	7.1	1.2	1.2	0.04	8.9	0.2	0.001	0.4
P value	0.020*	0.008*	0.278	0.270	0.843	0.003*	0.640	0.981	0.508
<b>Age (years)</b>									
$\leq 57$	27.7	26.5	21.3	45.8	18.7	16.1	33.5	4.5	12.3
$> 57$	12.7	32.0	15.3	45.3	32.7	27.3	27.3	4.0	11.3
Corrected $\chi^2$	9.7	0.9	1.4	0.0	7.1	5.0	1.1	0.00	0.0
P value	0.002*	0.347	0.232	1.000	0.008*	0.025*	0.292	1.000	0.942
<b>Marital status</b>									
Unmarried	10.8	35.4	16.9	43.1	30.8	24.6	18.5	7.7	13.8
Married	22.9	27.5	18.8	46.3	24.2	20.8	33.8	3.3	11.3
Corrected $\chi^2$	3.9	1.2	0.0	0.1	0.9	0.2	4.9	1.4	0.1
P value	0.047*	0.277	0.875	0.753	0.356	0.626	0.026*	0.231	0.720
<b>Employment</b>									
Unemployed	12.4	31.6	14.5	47.0	29.5	25.6	31.6	4.7	11.5
Employed	46.5	21.1	31.0	40.8	12.7	8.5	26.8	2.8	12.7
Corrected $\chi^2$	37.0	2.4	8.8	0.6	7.2	8.5	0.4	0.1	0.0
P value	$< 0.001^*$	0.120	0.003*	0.437	0.007*	0.004*	0.527	0.740	0.960
<b>Education</b>									
Uneducated	11.4	33.6	13.4	45.6	35.6	28.2	29.5	6.0	10.7
Educated	28.8	25.0	23.1	45.5	16.0	15.4	31.4	2.6	12.8
Corrected $\chi^2$	13.2	2.3	4.1	0.0	14.2	6.6	0.1	1.5	0.1
P value	$< 0.001^*$	0.129	0.042*	1.0	$< 0.001^*$	0.010*	0.816	0.162	0.700
<b>Income</b>									
$< 500$	16.7	26.7	21.7	54.2	20.8	23.3	40.0	5.8	8.3
$\geq 500$	22.7	30.8	16.2	40.0	28.6	20.5	24.3	3.2	14.1
Corrected $\chi^2$	1.3	0.4	1.1	5.3	1.9	0.2	7.7	0.6	1.8
P value	0.257	0.516	0.294	0.021*	0.163	0.663	0.005*	0.422	0.183
<b>Self-reported stages of physical activity</b>									
Not active	18.4	28.5	17.9	50.7	31.9	24.2	29.5	4.3	13.5
Active	24.5	30.6	19.4	34.7	12.2	16.3	32.7	4.1	8.2
Corrected $\chi^2$	1.2	0.1	0.0	6.2	12.5	2.0	0.2	0.00	1.4
P value	0.276	0.808	0.873	0.012*	$< 0.001^*$	0.161	0.667	1.0	0.244

\*Significant at  $P < 0.050$ .

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by Van Stralen.<sup>51</sup> This finding supports the need for programmes to help raise self-willpower/determination through stepped process of behaviour change from inactive (precontemplation) to active stages of PA (action and maintenance).<sup>52</sup> Interestingly, fear of injury was the only other reported barrier significantly different between individuals at inactive versus active stages of change in PA. This could be explained by possible physical constraints pertaining to older age<sup>49</sup> and existing comorbidities in the current study population triggering fear of injuries associated with PA.

Limited resources including high cost and limited facilities for PA have been reported as significant barriers to PA across different cultures.<sup>20,22</sup> In the current study, limited resources were reported as significant by individuals who were married and those with low income. Married individuals could have more financial commitments to their families especially in the Gulf Cooperation Council countries where extended families are common.<sup>53</sup> This may alter an individual's priorities for household income expenditure. Low income was similarly reported as a barrier in a Saudi population, possibly due to the perceived high cost of using PA facilities.<sup>14</sup> This may reflect a narrow view on what constitutes PA and a misconception that expensive equipment is required. Hence, irrespective of culture, interventions promoting cost-neutral PA such as walking in populations would be highly desirable to overcome this barrier.<sup>46,54</sup>

Lack of social support was frequently reported by females in this study. Meeting cultural norms and social expectations related to safety, security and conservative dress mainly for females were reported as barriers to PA in South Asian (Pakistani and Indian) British populations<sup>18,21</sup> and populations in Arabic countries such as Qatar.<sup>55</sup> Evaluation of interventions to provide the necessary social support and networks to PA specifically for women with T2D, particularly in the Gulf Cooperation Council countries, is warranted. Activities including group-based activities and buddying<sup>56-58</sup> are worth further investigation.

Other reported barriers such as fear of injury and lack of skills varied across subgroups in particular, older, unemployed and uneducated individuals. Older individuals with T2D are more vulnerable to have poor vision and osteoarthritic changes that may cause fall and injuries.<sup>59</sup> Moreover, the negative influence of pain to PA in older population with T2D was reported in Western countries,<sup>47</sup> and hence potential barriers to individuals' participation. These results suggest that programmes to promote PA should be individualised for type, frequency and intensity of PA and incorporate safety measures to prevent PA-induced pain and injuries in older individuals.<sup>60</sup>

Lack of time, on the other hand, has been a highly cited barrier to PA in the general population as well as populations with diabetes.<sup>15-18,21,22,47,61</sup> However, unlike the study by Alquaiz, significant scores for lack of time in this study were higher in males compared with females<sup>14</sup> along with a lack of energy, which may be a reflection of

the fact that more males than females were educated and employed. This perception of 'lack of time', in addition to family and social commitments, may jeopardise their time for PA, especially if individuals were younger and married. This discussion highlights the importance of changing people's perceptions of PA but also consideration of opportunities in other PA domains, namely work and travel, that could enable individuals with less leisure time to increase overall PA and behaviour.

Factors which are independent of an individual's decision-making, such as environment and religion, had no significant associations in the current study despite the hot weather during data collection of this study in April/May. These null results may be real or may be due to the wording of the questions and their interpretation. To address these gaps in the literature, a qualitative exploration of possible environmental, including seasonal variations, and religious factors affecting PA performance may be warranted.

Moreover, PCA showed cross-contribution of items/questions within lack of willpower, time, energy and skills indicating doubtful responses. Similarly, inputs from questions on lack of social support and lack of skills and energy were mixed. Future questionnaires on barriers to performing PA, especially in the Arabic-speaking countries, should consider more specific questions.

Additionally, results of this study cannot be generalised across all regions in Oman. More information is required from rural Omani communities where perceptions on PA may be different. Despite the excellent scale reliability measures in the current data, the results cannot be generalised due to possible differences in scale quality across various data.<sup>38</sup> Moreover, due to the cross-sectional design of this study, causal inferences cannot be drawn.

Finally, future attempts to explore barriers to PA should equally include work and travel domains to cater for diversities in both PA behaviour and sedentary lifestyle across subgroups of adults with T2D.

## CONCLUSION

This study identified lack of willpower, low resources and low social support (especially in females) as the most common barriers to performing leisure PA. The current findings can be used to inform the design of PA interventions for testing in clinical trials. The specific areas which might be usefully included to address barriers to performing PA are (1) assessment of individuals' readiness to change, (2) low-cost options for PA resources and social support, (3) approaches aimed at increasing individuals' understanding of what constitutes PA and (4) methods that are flexible and tailored to the specific needs of subgroups of adults with T2D. In addition, approaches that enhance self-efficacy (and will power) and social support should be included.

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evaluation. TS prepared the initial draft of the manuscript and all other authors have contributed. All authors have critically reviewed and approved the final version of the manuscript.

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## Perceived barriers to leisure time physical activity in adults with type 2 diabetes attending primary healthcare in Oman: a cross-sectional survey

Thamra Alghafri, Saud M Alharthi, Yahya Mohd Al Farsi, Elaine Bannerman, Angela Mary Craigie and Annie S Anderson

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## Appendix 4.3: Ethical approval for all the formative work



School of Psychology

**University of Dundee Research Ethics Committee**

Angela Craigie,  
Centre for Public Health Nutrition Research,  
Division of Cancer Research,  
College of Medicine, Dentistry & Nursing,  
University of Dundee,  
Dundee,  
DD1 4HN.

18 March 2015

Dear Dr Craigie,


Thank you for providing a copy of the approval letter from Sultanate of Oman Ministry of Health Research and Ethical Review Committee for the research project, 'Physical Activity among Omani Patients with Type 2 Diabetes Attending Primary Health Care Facilities in Muscat, Oman'.

I am pleased to confirm that the University of Dundee Research Ethics Committee has given reciprocal approval for this project.

This decision is based on the following documents you provided:

1. Phase 1 Questionnaire 18 March 2015
2. Study protocol 13 March 2014 V2
3. Phase 1 questionnaire PIS and consent -V2 UREC
4. Phase 2 Focus group PIS and consent V2
5. MOH Oman Approval letter Dr Thamra Al -Gahfri 18032015
6. UREC reciprocal approval application 18 March 2015

Yours sincerely,



Dr Peter Willatts  
Vice-Chair, University of Dundee Research Ethics Committee

**Peter  
Willatts**

Digitally signed by Peter Willatts  
DN: cn=Peter Willatts,  
o=University of Dundee,  
ou=School of Psychology,  
email=p.willatts@dundee.ac.uk,  
c=GB  
Reason: I am the author of this  
document  
Date: 2015.03.18 14:08:05 +01'00'

College of Art and Social Sciences UNIVERSITY OF DUNDEE Dundee DD1 4HN Scotland UK  
t +44(0)1382 384622/3 f +44 (0) 1382 229993 e h.henderson@dundee.ac.uk www.dundee.ac.uk/psychology  
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**Sultanate of Oman**

MINISTRY OF HEALTH

Directorate General of Health Services

GOVERNORATE OF MUSCAT

*Director General Office*Ref: MH/DGHS/DG/294/15  
March, 2015سلطنة عُمان  
وزارة الصحة

المديرية العامة للخدمات الصحية

إحافضة مسقط

مكتب المدير العام

To : Directors of health services- All willayates

**Subject: Research Project**

After Compliments,

Kindly be informed that Dr.Thamra Al.Ghafri is conducting a research on "Physical Activity among Omani Patients with Type 2 Diabetes Attending Primary Health Care Facilities in Muscat" as part of her PhD. Her research has been approved by the central ethical research committee as well as the ethical committee at Dundee University (copy attached). You are kindly requested to facilitate her work.

With kind regards,

  
Dr. Fatma Al-Ajmi  
Director General


Cc:

P.O. Box : 358, Mina Al-Fahal  
Postal Code : 116, Sultanate of Oman  
Tel. : 24782104 - Fax : 24782102

ص.ب : ٣٥٨ ميناء الفحل - مسقط  
الرمز البريدي : ١١٦، سلطنة عُمان  
هاتف : ٢٤٧٨٢١٠٤، فاكس : ٢٤٧٨٢١٠٢

*Sultanate of Oman*  
*Ministry of Health*  
*Directorate General of Planning*  
*and Studies*



سلطنة عُمان  
 وزارة الصحة  
 المديرية العامة للتخطيط  
 والدراسات

Ref. : MH/DGP/R&S/PROPOSAL\_APPROVED/15/2015

Date. : 16.03.2015

DR. Thamra Al-Ghafri  
 Principal Investigator

Study Title: " Physical Activity among Omani Patients with Type 2 Diabetes Attending Primary Health Care Facilities in Muscat, Oman"

After compliments

We are pleased to inform you that your research proposal " Physical Activity among Omani Patients with Type 2 Diabetes Attending Primary Health Care Facilities in Muscat, Oman" has been approved by Research and Ethical Review and Approve Committee, Ministry of Health.

Regards,

أحمد محمد القاسمي

Dr. Ahmed Mohamed Al Qasmi  
 Director General of Planning and Studies  
 Chairman, Research and Ethical Review and Approve Committee  
 Ministry of Health, Sultanate of Oman.



Cc  
 Day file

## Appendix 4.4: The questionnaire for the formative work



### Physical Activity among Omani Patients with Type 2 Diabetes Attending Primary Health Care Facilities in Muscat, Oman

Before starting make sure that your client (by the interviewer):

Is a patient with type 2 diabetes.

Is 18 years old or over.

Has had no less than 2 years follow up in the diabetes clinic in the health center.

Has read the information sheet and signed the consent form

Day of the interview D/ M/ Y-----

Time commenced----- :-----

Interviewers name:

Physical Activity among Omani Patients with Type 2 Diabetes Attending  
Primary Health Care Facilities in Muscat, Oman study. Formative questionnaire  
(March 2015)

**Part 1: Medical history (this part will be filled by the interviewer from the patient's last visit from the Al-shifa electronic system before commencing the questionnaire):**

- Date of birth: D/ M/ Y:\_\_\_\_\_ age :\_\_\_\_\_
- Gender: 1-Male /2- Female
- Date of last visit to diabetes clinic D/ M/ Y: \_\_\_\_\_
- Year of diagnosis of diabetes : \_\_\_\_\_

Please tick the source of your answer:

From Al-shifa system ☐ (if not available please ask the patient)

Reported by the client ☐

Other medical (co-existing) chronic conditions or complications of diabetes:

	Cardiovascular disease ----specify (e.g: hypertension, heart failure, coronary heart disease, cardiomyopathies, stroke)
	Renal disease -----specify (e.g: renal failure, high GFR)
	Thyroid disease----specify (e.g: hypothyroid, hyper thyroid , cancer , thyroid nodule)
	Musculoskeletal ---specify (e.g: osteoarthritis)
	Eye -----specify (e.g: retina problems, glaucoma, cataract)
	Foot ---- specify (e.g: amputation, ulcer)
	Other ----- specify

Please list your current medications, doses and date commenced:

Name of medicine	Dose	Date commenced

Please list the most recent measurements recorded:

	Measurement	Date of recording
Weight (kg)		
Height (cm)		
BMI (kg/m <sup>2</sup> )		
Waist Hip Ratio (WHR) if available		
Glycated Hb		
Fasting glucose level		
Systolic BP (mm Hg)		
Diastolic BP (mm Hg)		
Total cholesterol		
HDL		
LDL		
Triglycerides		

Physical Activity among Omani Patients with Type 2 Diabetes Attending  
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(March 2015)

## Part 2: Importance of physical activity to the participant

Do you think you are doing enough physical activity?

Yes

No

Do you think that physical activity could improve your diabetes?

Yes

No

Would you like to increase your physical activity levels?

Yes

No

Why?

## Part 3: What types of physical activity do you prefer? (rate them in order if more than one, from 1=most preferred)

Walking
Swimming
Cycling
Running
Going to the Gym
Other : specify

**Part 4: Physical activity data from the WHO (GPAQ)**

Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person. Think first about the time you spend doing work (paid or unpaid) e.g. study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment.

In answering the following questions:

'Vigorous-intensity' activities require hard physical effort and cause large increases in breathing or heart rate.

'Moderate-intensity' activities require some physical effort and cause noticeable increases in breathing or heart rate.



Questions		Response
<b>Activity at work (excluding travel to and from work)</b>		
1	Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate [like carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously?	1. Yes  2. No <i>If No, go to Q 4</i>
2	In a typical week, on how many days do you do vigorous-intensity activities as part of your work?	Number of days <input type="text"/>
3	How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours : <input type="text"/> : <input type="text"/> minutes <u>hrs</u> mins
4	Does your work involve moderate-intensity activity that causes noticeable increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously?	1. Yes  2. No <i>If No, go to Q 7/</i>
5	In a typical week, on how many days do you do moderate-intensity activities as part of your work?	Number of days <input type="text"/>
6	How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours : <input type="text"/> : <input type="text"/> minutes <u>hrs</u> mins
<b>Travel to and from places (including to and from work)</b>		
The next questions exclude the physical activities at work that you have already mentioned. Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to place of worship.		
7	Do you walk or use a bicycle ( <i>pedal cycle</i> ) for at least 10 minutes continuously to get to and from places?	1. Yes  2. No <i>If No, go to Q 10</i>

8	In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days _____
9	How much time do you spend walking or bicycling for travel on a typical day?	Hours : _____ : _____ minutes hrs mins
<b>Recreational activities</b> <b>The next questions exclude the work and transport activities that you have already mentioned. Now I would like to ask you about sports, fitness and recreational activities (leisure).</b>		
10	Do you do any vigorous-intensity sports, fitness or recreational ( <i>leisure</i> ) activities that cause large increases in breathing or heart rate [ <i>like running or football</i> ] for at least 10 minutes continuously?	1. Yes  2. No <i>If No, go to Q 13</i>
11	In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational ( <i>leisure</i> ) activities?	Number of days _____
12	How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	Hours : _____ : _____ minutes hrs mins
13	Do you do any moderate-intensity sports, fitness or recreational ( <i>leisure</i> ) activities that cause noticeable increases in breathing or heart rate for at least 10 minutes continuously?	1. Yes 2. No
14	In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational ( <i>leisure</i> ) activities?	Number of days _____
15	How much time do you spend doing moderate intensity sports, fitness or recreational activities on a typical day?	Hours : _____ : _____ minutes hrs mins
<b>Sitting time</b> <b>The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent [sitting at a desk, sitting with friends, travelling in car, bus, train, reading, playing cards or watching television], but do not include time spent sleeping.</b>		
16	How much time do you usually spend sitting or reclining on a typical day?	Hours : _____ : _____ minutes hrs mins

Were you ever given advice on physical activity in your health center as part of your diabetes care?

Yes

No

If yes,

How frequently?

- 1- Very frequently (in every visit to diabetes clinic)
- 2- Somewhat frequently (2 times or more in a year- regularly)
- 3- Somewhat infrequently (once a year- regularly)
- 4- Not at all frequently (not regular through the years)

By whom?

- 1- Doctor
- 2- Nurse
- 3- Dietitian
- 4- Health educator
- 5- Others  
(specify).....

Was it helpful in increasing your physical activity levels?

Yes

No

Which of the following describes your current physical activity status

- 1- Not ready.
- 2- Getting ready to be regularly active in the next 6 months.
- 3- Ready to be regularly active in the next 30 days (Preparation).
- 4- Regularly active for <6 month (Action).
- 5- Regularly active for  $\geq 6$  months (Maintenance).

### Part 5: Barriers to physical activity

How likely are you to say?	Very likely	Somewhat likely	Somewhat unlikely	Very unlikely
	3	2	1	0
1. My day is so busy now, I just don't think I can make the time to include physical activity in my regular schedule.				
2. None of my family members or friends like to do anything active, so I don't have a chance to exercise.				
3. I'm just too tired after work to get any exercise.				
4. I've been thinking about getting more exercise, but I just can't seem to get started				
5. I'm getting older so exercise can be risky.				
6. I don't get enough exercise because I have never learned the skills for any sport.				
7. I don't have access to jogging trails, swimming pools, bike paths, etc.				
8. Physical activity takes too much time away from other commitments—time, work, family, etc.				
9. I'm embarrassed about how I will look when I exercise with others.				
10. I don't get enough sleep as it is. I just couldn't get up early or stay up late to get some exercise.				
11. It's easier for me to find excuses not to exercise than to go out to do something.				
12. I know of too many people who have hurt themselves by overdoing it with exercise.				
13. I really can't see me learning a new sport at my age.				

14. It's just too expensive. You have to take a class or join a club or buy the right equipment.				
15. My free times during the day are too short to include exercise.				
16. My usual social activities with family or friends do not include physical activity				
17. I'm too tired during the week and I need the weekend to catch up on my rest.				
18. I want to get more exercise, but I just can't seem to make myself stick to anything.				
19. I'm afraid I might injure myself or have a heart attack.				
20. I'm not good enough at any physical activity to make it fun.				
21. If we had exercise facilities and showers at work, then I would be more likely to exercise.				
22. my religious believes are not supportive for PA				
23.extreme hot weather is an obstacle				
24.sports cloths are not culturally appropriate				
25.PA in the summer times is not convenient to me				
26.My religious thoughts are against performing PA				
27.the environment around be is not supportive for PA				

Are there any other barriers you would like to declare?

- 1- Social barriers (specify)
- 2- Religious barriers (specify)
- 3- Environmental barriers (specify)
- 4- Financial barriers (specify)
- 5- Barriers related to diabetes (specify)

Physical Activity among Omani Patients with Type 2 Diabetes Attending  
Primary Health Care Facilities in Muscat, Oman study. Formative questionnaire  
(March 2015)

6- Others (specify)

**Part 6: Physical activity in the routine type 2 diabetes care health center**

Do you think physical activity services should be part of your routine visit to the diabetes clinic in the health center?

Yes

No

If yes,

Please suggest ways to include physical activity in diabetes clinic in health centers?

Within the diabetes clinic in the health center, who in your opinion should be responsible of physical activity services? Please tick

Diabetes doctors ☐

Diabetes nurses ☐

Dietitians ☐

Health educators ☐

Pharmacists ☐

Others (specify) ☐

**Part 7: Would you be willing to be contacted about participating in a future study to test the effectiveness of a physical activity programme within health centers?:**

Yes ☐

2- No ☐

If yes, please provide contact details on the final page

Physical Activity among Omani Patients with Type 2 Diabetes Attending Primary Health Care Facilities in Muscat, Oman study. Formative questionnaire (March 2015)

**Part 8: Demographic data:****Marital status**

Never married
Currently married
Separated / Divorced
Widowed

**Education**

Less than primary school
primary school completed
Preparatory /Secondary school completed
College completed
University completed
Post graduate degree completed

**Household Income per month** (income of all household members, and from all sources (including benefits))

< 500 Omani rials
500 - <1000
1000 - <1500
1500 - <2000
>=2000
77 Don't Know
88 Prefer not to answer



Working status (you can select more than one answer)

Government employee		
Non-government employee		
Self-employed		
Non-paid		
Student:	Full-time	Part-time
Retired		
Unemployed (able to work)		
Unemployed (unable to work)		
Prefer not to answer		

Time of completion:

Thank you

If you stated that you would be willing to be contacted about participating in a future study to test the effectiveness of a proposed physical activity programme within health centers, please provide your contact details below.

Please note, there will be no obligation to take part.

Name :

Address :

Contact number :

Physical Activity among Omani Patients with Type 2 Diabetes Attending Primary Health Care Facilities in Muscat, Oman study. Formative questionnaire (March 2015)

## Appendix 4.5: Training Agenda for the formative study



### **Physical Activity among Omani Patients with Type 2 Diabetes Attending Primary Health Care Facilities in Muscat, Oman Agenda of training 9<sup>th</sup> April**

Venue: Directorate of Health services training hall, Muscat

Objectives:

1. To train members of the data collection team on the components of the study questionnaire.
2. To ensure common understanding of the questions, ways of recording and pilot practice.
3. To discuss logistics and the overall process of data collection in the health centres.
4. To conduct practical sessions (simulations) on data collection to resolve any confusing issues.

Speakers:

Dr. Moosa Al-Subhi (physical activity officer in Ministry of Health, Oman)

Dr. Thamra Alghafri, the project principal investigator

Topic	Time	Speaker
10 minutes		
Short video on PA		
Definitions  Physical activity  Exercise  Sports	8:30-8: 50	Dr.Moosa Al-Subi
Effectiveness PA and T2D	8:55- 9:15	Dr. Thamra AlGhafri
Global Physical activity Questionnaire (GPAQ)  Data recording	9:16- 9: 30	Dr.Moosa Al-Subi
Role play 1 (working in two)	9:30-10:00 am	
Break		
Barrier Questionnaire  Purpose of questions  Items included  recording data	10:30-11:00	Thamra AlGhafri
Role play 2(working in two)	11:00-11:30	The team
Patient information sheets and consent forms	11:31-11:45	
Review of all parts of the questionnaire  Purpose of questions.  Comprehension of all items by interviewers.	11:46-12:30	The team

Guidance on optimal questioning.  Recording notes.  Recording styles.  Pilot practice.  (Simulation session)		
Data collection process and management of logistics	12:31-1:00	The team
Question and Answer (Q&A)	1:01-1:30	The team
<p>Closing remarks</p> <p>Ms.Samiya Al-Bulushi will be responsible to:</p> <p>Ensure that training procedures are covered in the training.</p> <p>Adhere to Oman Medical Speciality Board (OMSB) guidelines of conducting trainings.</p> <p>Cross check on data collection in the field.</p>		

#### List of Participants:

1. Ahlam Al-Rumhi (staff nurse)
2. Ibtisam Al-Shidhani (staff nurse)
3. Dr.Hasina Al-Harhi
4. Dr.Bader Al-Alawi
5. Khadija Al-Dharmaky (Medical orderly)
6. Ashwaq Al-Harhi (Dietitian)

## Appendix 4.6: Quality check list for the formative work



### Quality Audit Checklist on Training and Data collection for the Study of Physical Activity among Omani Patients with Type 2 Diabetes Attending Primary Health Care Facilities in Muscat, Oman

Ms.Samiya Al-Bulushi (Masters of Medical Education from university of Dundee)

Description	Completeness of data		
	Fully	Partial	Incomplete
	3	2	1
Inclusion criteria reviewed and participants selected accordingly			
Is a patient with type 2 diabetes.			
Is 18 years old or over.			
Has had no less than 2 years follow up in the diabetes clinic in the health center.			
Has read the information sheet and signed the consent form			
Part 1: Medical history (this part filled by the interviewer from the patient's last visit from the Al-shifa electronic system before commencing the questionnaire)			
Date of birth			
Gender			
Date of last visit to diabetes clinic			

Year of diagnosis of diabetes			
Other medical (co-existing) chronic conditions or complications of diabetes			
list of current medications, doses and date commenced			
list of the most recent measurements recorded:			
Weight (kg)			
Height (cm)			
BMI (kg/m <sup>2</sup> )			
Waist Hip Ratio (WHR) if available			
Glycated Hb			
Fasting glucose level			
Systolic BP (mm Hg)			
Diastolic BP (mm Hg)			
Total cholesterol			
HDL			
LDL			
Triglycerides			
Part 2: Importance of physical activity to the participant			
Do you think you are doing enough physical activity?			
Do you think that physical activity could improve your diabetes?			
Would you like to increase your physical activity levels?			
Why			
Part 3: What types of physical activity do you prefer			
Part 4: Physical activity data from the WHO (GPAQ)			

Does your work involve more of sitting or a continuous less than 10 minutes standing or walking?			
Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate [like carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously?			
In a typical week, on how many days do you do vigorous-intensity activities as part of your work?			
How much time do you spend doing vigorous-intensity activities at work on a typical day?			
Does your work involve moderate-intensity activity that causes noticeable increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously?			
In a typical week, on how many days do you do moderate-intensity activities as part of your work?			
How much time do you spend doing moderate-intensity activities at work on a typical day?			
How much time do you work in a regular day?			
Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?			
In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?			
How much time do you spend walking or bicycling for travel on a typical day?			
Does your recreational time involve more of sitting/ lying down or less than 10 minutes continues Physical activity?			
Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate [like running or football] for at least 10 minutes continuously?			
In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities?			
How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?			
Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause noticeable increases in breathing or heart rate for at least 10 minutes continuously?			



In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities?			
How much time do you spend doing moderate intensity sports, fitness or recreational activities on a typical day?			
How much time do you usually spend sitting or reclining on a typical day?			
Were you ever given advice on physical activity in your health center as part of your diabetes care?			
How frequently?			
By whom?			
Was it helpful in increasing your physical activity levels?			
Which of the following describes your current physical activity status?			
Part 5: Barriers to physical activity			
My day is so busy now, I just don't think I can make the time to include physical activity in my regular schedule.			
None of my family members or friends like to do anything active, so I don't have a chance to exercise.			
I'm just too tired after work to get any exercise.			
I've been thinking about getting more exercise, but I just can't seem to get started			
I'm getting older so exercise can be risky.			
I don't get enough exercise because I have never learned the skills for any sport.			
I don't have access to jogging trails, swimming pools, bike paths, etc.			
Physical activity takes too much time away from other commitments—time, work, family, etc.			
I'm embarrassed about how I will look when I exercise with others.			
I don't get enough sleep as it is. I just couldn't get up early or stay up late to get some exercise.			

It's easier for me to find excuses not to exercise than to go out to do something.			
I know of too many people who have hurt themselves by overdoing it with exercise.			
I really can't see me learning a new sport at my age.			
It's just too expensive. You have to take a class or join a club or buy the right equipment.			
My free times during the day are too short to include exercise.			
My usual social activities with family or friends do not include physical activity			
I'm too tired during the week and I need the weekend to catch up on my rest.			
I want to get more exercise, but I just can't seem to make myself stick to anything.			
I'm afraid I might injure myself or have a heart attack.			
I'm not good enough at any physical activity to make it fun.			
If we had exercise facilities and showers at work, then I would be more likely to exercise.			
Other Barriers asked			
Part 6: Physical activity in the routine type 2 diabetes care health center			
Do you think physical activity services should be part of your routine visit to the diabetes clinic in the health center?			
Please suggest ways to include physical activity in diabetes clinic in health centers?			
Within the diabetes clinic in the health center, who in your opinion should be responsible of physical activity services?			
Part 7: Willingness to be contacted for further participation			
Part 8: Demographic data			
Marital status			
Education			
Income			

Work status			
Overall completeness of the questionnaire			
Score			
$\geq 180$ = fully complete			
130 - $< 180$ = partially complete			
80 - $< 130$ = incomplete			

### Appendix 4.7: Correlates of meeting physical activity recommendations across work, travel and leisure domains

(%)	Work					Travel					Leisure				
	Meetin g 14(4.6)	Not meeting 291(95.4)	OR	CI	Sig	Meeting 29(9.5)	Not meeting 276(90.5)	OR	CI	Sig.	Meeting 37(12.1)	Not meeting 268(87.9 )	OR	CI	Sig.
Gender															
Male 130(42.6)	8(6.2)	122(93.8)	0.97	0.9-1.0	0.2	24(18.5 )	106(81.5)	9.2	3.2- 25.9	<0.001**	24(18.5)	106(81.5 )	3.1	1.4-6.6	0.005*
Female 175(57.4)	6(3.4)	169(96.6)	Ref	.	.	5(2.9)	170(97.1)	Ref	.	.	13(7.4)	162(92.6 )	Ref	.	.
Age															
≤57 155(50.8)	9(5.8)	146(94.2)	0.97	0.9-1.0	0.3	20(12.9 )	135(87.1)	3.1	1.3-7.6	0.01*	27(17,4)	128(82.6 )	3.1	1.4-7.1	0.006*

>57 150(49.2)	5(3.3)	145(96.7)	Ref	.	.	9(6.0)	141(94.0)	Ref	.	.	10(6.7)	140(93.3) )	Ref	.	.
Self-reported stages of PA															
Preparation/action/maintenance 98(32.1)	10(10.2) )	88(89.8)	4.8	1.4-15.8	0.01*	9(9.2)	89(90.8)	0.9	0.9-1.1	0.9	26(26.5)	72(73.5)	5.5	2.5-12.0	<0.001**
Not/getting ready 207(67.9)	4(1.9)	203(98.1)	Ref	.	.	20(9.7)	187(90.8)	Ref	.	.	11(5.3)	196(94.7) )	Ref	.	.
Reporting barriers to performing PA															
No barriers 128(42.0)	11(8.6)	117(98.3)	4.4	1.2-16.5	0.03*	19(14.8) )	109(85.2)	2.5	1.1-5.8	0.03*	22(17.2)	106(91.5) )	0.9	0.9-1.0	0.8
Reported barriers 177(58.0)	4(1.7)	173(98.3) 0	Ref	.	.	10(5.6)	167(94.4)	Ref	.	.	15(8.5)	162(91.5) )	Ref	.	.

## **Appendix 4.8: Factor analysis of the English to Arabic translated questionnaire on barriers to performing leisure time physical activity**

### **Factor analysis and reliability test results**

Initially, the factorability of the 27 items/questions was examined. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.711, above the commonly recommended value of 0.600. Bartlett's test of sphericity (test of at least one significant correlation between 2 of the items studied) was also significant ( $\chi^2(351) = 2600.175, p < .05$ ) (Tobias and Carlson, 1969). The communalities (proportion of item's variance explained by the extracted factors) were all above 0.300, further confirming that each item shared some common variance with other items. Given these overall indicators, factor analysis was regarded to be suitable with all the 27 items/questions.

PCA for 9 components solution namely lack of willpower/time/energy and skills, fear of injury, lack of time/ lack of energy, environmental barriers, religious barriers, lack of willpower, lack of skills/ social support and lack of resources, explained 13.1%, 11.4%, and 9.2%, 9.0%, 7.2%, 5.1%, 4.3%, 3.8% and 3.6% of the variance respectively.

None of the 27 items were eliminated because they all met a minimum criteria of having a primary factor loading (how much a factor explains a variable) of 0.4 or above. Solutions for the nine components were examined using Oblimin rotation of the factor loading matrix. The factor loading matrix for this final solution is presented in Table 1. All factor loadings were in the same direction of the barrier categories used in the current study where a set of three items instructed a barrier category mainly component 2, 4, 5, 6, and 9 representing fear from injury, environmental barriers, religious barriers, lack of willpower, and lack of resources respectively. However, cross contributions were evident in four out of the nine extracted components namely component 1 (lack of willpower, time, energy and skills), component 3(lack of time and energy), component 7 (lack of social support and skills), and component 8 (lack of social

support and energy). Component correlation matrix, presented in table 2, shows week correlations between the extracted nine components  $<0.200$  except for the correlations of 0.201 and -0.204 between component 6 (lack of willpower) with 7 (combination of lack of skills and social support) and 2 (fear of injury) with 9 (lack of resources) respectively.

McDonald's coefficient Omega was equal to 0.750 indicating moderate reliability of the 27 items/questions scale. (Dunn et al., 2014)

Table 1: The extracted components and factor loadings based on a principal components analysis with Oblimin rotation for the 27 items/questions used in the current study (N = 305)

Items/ questions	Extracted components (1-9)*								
	1	2	3	4	5	6	7	8	9
Q4	.503					-.502			
Q19		.879							
Q12		.801							
Q5		.791							
Q1			.745						
Q15			.743						
Q17			.721						
Q3	.351		.604						
Q8	-.423		.468						
Q24				.922					
Q26				.909					
Q22				.839					
Q25					.899				
Q23					.871				

Q27					.777				
Q20						-.788			
Q11									
Q18						-.748			
Q16							-.789		
Q13							-.712		
Q6	.470						-.538		
Q2							-.390		
Q9								.819	
Q10	.383							.622	
Q14									.802
Q7									.765
Q21									.761

\*1=lack of willpower/energy/time/skills, 2=fear of injury, 3=lack of time/ lack of energy,  
 4=environmental barriers, 5=religious barriers, 6=lack of willpower, 7=lack of skills/ social  
 support, 8=lack of energy/social support and 9=lack of resources.



Table 2: Component correlation matrix

Extracted components*	1	2	3	4	5	6	7	8	9
1	1.000	-.008	.017	.028	-.046	-.151	-.049	.020	.149
2	-.008	1.000	-.099	-.023	.025	-.028	-.199	.000	-.204
3	.017	-.099	1.000	.063	-.117	-.127	-.043	.145	.009
4	.028	-.023	.063	1.000	.014	.004	-.016	.051	.019
5	-.046	.025	-.117	.014	1.000	.062	-.014	-.034	-.021
6	-.151	-.028	-.127	.004	.062	1.000	.207	-.153	-.125
7	-.049	-.199	-.043	-.016	-.014	.207	1.000	-.134	-.009
8	.020	.000	.145	.051	-.034	-.153	-.134	1.000	.014
9	.149	-.204	.009	.019	-.021	-.125	-.009	.014	1.000

\*1=lack of willpower/energy/time/skills, 2=fear of injury, 3=lack of time/ lack of energy, 4=environmental barriers, 5=religious barriers, 6=lack of willpower, 7=lack of skills/ social support, 8=lack of energy/social support and 9=lack of resources.

Further Factor analysis and reliability tests were conducted on the studied barrier subscales (3 questions per barrier). Table 3 provide factor loadings and McDonald's coefficient Omega for all the nine subscales used in the current study indicating excellent sub-scale quality.

Table 3: Factor loadings and McDonald's coefficient Omega for the study subscales

Barrier categories	Items/questions	factor loadings	Omega
Lack of time	Q15	0.826	0.900
	Q1	0.798	
	Q8	0.618	
Lack of social support	Q16	0.734	0.900
	Q2	0.680	

	Q9	0.534	
Lack of energy	Q3	0.755	0.900
	Q17	0.720	
	Q10	0.581	
Lack of willpower	Q18	0.837	0.900
	Q4	0.746	
	Q11	0.691	
Fear of injury	Q19	0.904	0.900
	Q12	0.823	
	Q5	0.803	
Lack of skills	Q6	0.840	0.900
	Q13	0.646	
	Q20	0.560	
Lack of resources	Q7	0.837	0.900
	Q21	0.831	
	Q14	0.754	
Religious barriers	Q25	0.905	0.900
	Q23	0.872	
	Q27	0.786	
Environmental barriers	Q24	0.924	0.900
	Q26	0.913	
	Q22	0.847	

## Appendix 5.1: Published study (3) “Health professionals’ perception about physical activity promotion in diabetes care within primary health care settings in Oman



University of Dundee

### Health professionals’ perceptions about physical activity promotion in diabetes care within primary health care settings in Oman

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widen current opportunities. In the presence of various diabetes primary care providers, the potential for dietitians to include individualised PA consultations as part of their role was highlighted. Participants felt that consultations should be augmented by approaches within the community (volunteer support and/or appropriate facilities). However, despite lack of experience with technology supported approaches and motivational tools, the telephone application “WhatsApp” and use of pedometers were considered potentially suitable. The need for training in behaviour change techniques and clearly communicated intervention guidelines was emphasised.

**Conclusions:** A multi-component approach including PA consultations, possibly led by trained dietitians, technological routes for providing support along with community mapping for resources appear to offer promising approaches for further PA intervention studies within diabetes primary health care.

**Keywords:** Public health, Health profession, Evidence-based medicine

## 1. Introduction

Type 2 diabetes (T2D) is a global health problem especially in the Middle East and North Africa (MENA) region including countries of the Gulf Cooperation Council (GCC), including Oman. Globally, the number of people with diabetes is expected to increase from 415 million adults to 642 million by the year 2040 [1]. In Oman, estimated prevalence of diabetes has increased considerably from 12.3% in 2008 to 14.8% in 2015, exceeding global rates [1, 2, 3]. It is therefore essential that effective management strategies are developed to better manage diabetes.

Physical activity (PA) is fundamental in the management of T2D [4, 5]. Extensive research across diverse populations has reported significant effects of PA in both prevention and control of diabetes. Moderate increases in PA have been shown to reduce HbA1c, and improve insulin sensitivity, fat oxidation and lipid storage in muscle [6]. In Oman, the best available evidence on prevalence of meeting PA recommendations in adults with T2D is 15% [7]. More recently, formative work undertaken to explore PA in diabetes care using the Global Physical activity Questionnaire (GPAQ) [8] showed that only 21% of adults with T2D met the World Health Organizations’ (WHO) recommended levels of PA [9]. These rates are considerably less than those reported in populations with T2D in the UK (34%) [10] and USA (36 to 50%) [11] and are of great concern.

Diabetes management in Primary Health Care (PHC) in Oman is managed by a multi-disciplinary team of health professionals (HPs) namely doctors, nurses, dietitians, and health educators. Current Omani diabetes management guidelines [12] recommend that PA is to be discussed with all patients, but the level of awareness and indeed implementation of these guidelines by health professionals (HPs) is unknown. Globally, evidence on PA promotion indicates that it remains an

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# Health professionals' perceptions about physical activity promotion in diabetes care within primary health care settings in Oman

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## Abstract

**Background:** As part of formative work to inform an interventional design to increase physical activity (PA) in patients with type 2 diabetes in Oman, this qualitative study aimed to determine health professionals' perception of barriers and opportunities, personnel responsibilities and plausible PA promotional approaches.

**Methods:** Four focus group discussions were carried out with groups of health care professionals (family physicians, dieticians and health educators, managers and general practitioners). All discussions were audio recorded and transcribed. Responses were analysed using a thematic analysis.

**Results:** Barriers to PA reported by participants (n = 29) were identified at three levels: health care system (e.g. deficient PA guidelines); individual (e.g. obstructive social norms) and community (e.g. lack of facilities). Participants felt that a multilevel approach is needed to address perceived barriers and to

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under-used component in diabetes care [13]. Only a small number of studies have reported any PA counseling by diabetes HPs and this appears to have been due to lack of time, confidence, knowledge, training, and resource to provide ongoing support [14, 15, 16, 17, 18].

However, a number of methods of reinforcing PA promotion in diabetes primary care have been evaluated and shown to be effective and feasible [5, 19]. PA interventions for adults with T2D can be delivered in a clinical or community practice context, and can be provided in various settings, by various professionals, using various modes of delivery [20]. However, there is no consensus on what are the optimal PA intervention components. Significant improvements in glycaemic control are associated with interventions of longer duration (e.g. 6–12 months) [21], or where PA advice is combined with dietary advice [22]. Furthermore, PA consultations linked to a theoretical framework of behaviour change and tailored to the needs of individuals with T2D are more effective than more general PA advice [20].

On the other hand, pedometers have been widely reported as an effective follow up and monitoring tool to increase PA behaviour [23]. An intervention in Belgium using pedometers in a population with T2D showed them to be successful in increasing the number of steps with subsequent improvements in patients' blood pressure [24].

However, the majority of the research to date has been undertaken in controlled research environments, mainly in western countries [21]. Little is known if these interventions work if undertaken in everyday practice, especially in Arabic speaking countries where culture, tradition and health care settings are distinct. The current study aimed to determine the perceptions of HPs on PA promotion for adults with T2D within a local clinical primary care setting in Oman. Specifically, it aimed to explore the following (with respect to PA promotion) objectives:

- The perceived barriers and opportunities
- Who should be responsible for the delivery of PA interventions
- The perceived intervention components that could possibly be implemented
- The required resources/actions to integrate PA in diabetes care

## 2. Methods

### 2.1. Setting and conceptual framework

As part of a series of studies to inform a PA intervention design for adults with T2D [9, 25] including the exploration of barriers to performing physical activity in patients with T2D, the current study presents the results of four focus group discussions (FGDs) conducted in June–July 2015 to explore perceptions of HPs from different disciplines on possible PA interventions within routine diabetes



primary care [14]. Planning a feasible PA intervention within a clinical setting requires the views of health care providers at different health care levels [26]. Hence, this approach was guided by an ecological model of health behaviour [27], and a literature review was undertaken. Focus group discussions were chosen over in-depth interviews, because it was felt that the dynamic group interactions would allow better insights across group disciplines [28].

This qualitative research is based on an interpretative phenomenological analysis (IPA) method of understanding a group's perception of a particular topic using purposeful sampling [29].

## 2.2. Participants

Participants were recruited because they were healthcare professionals currently involved in the delivery of aspects of the diabetes care service in Oman. To ensure sufficient diversity of opinion, HPs involved in diabetes primary care from multiple disciplines (family physicians, dieticians, health educators, health managers and general practitioners) were recruited to the FGDs (participants of the same discipline in each group). The aim was to recruit between six and ten participants per focus group [28]. Participants (doctors, dieticians, health educators, and nurses) in all health centres in Muscat region were invited by written request by the Director of Primary Health Care in the Directorate of Health Services. The invitation letter was addressed to the head of each health centre to inform the potential participants about the date and venue of the FGDs and invite them to take part in the discussions. Subsequently, a list of staff who were willing to participate was sent to the Director of Primary Health Care and shared with the primary investigator (TSA) of this study. An information sheet describing the study and summarizing the available evidence from Oman [15, 30, 31] was shared with the participants as part of their invitation letters. The information provided included evidence on low levels of PA and high prevalence of non-communicable diseases, particularly diabetes, in the Omani population. This was expected to encourage participation and build interest on the subject. Follow-up telephone calls were made to arrange a time and place for the interviews. Although Arabic was the mother tongue for all participants, all interviews were conducted in English, since it is the common working language in the health sector in Oman.

## 2.3. Methodological approach

All focus groups were organised in a conference room with a semi-circle sitting arrangement at a time and date convenient for the participants and researchers. All participants provided informed consent. The focus groups, lasting 60–150 min, were led by a trained facilitator (TSA) and assistant facilitator (SA), audio-recorded and subsequently transcribed. The assistant facilitator took notes during

the discussions and made sure the facilitator did not overlook any participants trying to add comments. Discussions continued until saturation of new information was reached.

## 2.4. Topic guide

A semi-structured topic guide contained prompt questions eliciting participants' perceptions on the barriers and opportunities to promote PA in diabetes care, and their suggestions on allocation of responsibilities, possible intervention components and required resources/actions (see Table 1) [28]. The topic guide was then reviewed by the research team, and pilot-tested in a mixed group of six health professionals (one doctor, one nurse, two health educators and two dietitians). Changes were made to ensure common understanding and dynamic discussion. Because the pilot FGD revealed that participants were not fully aware of the common PA terminologies for intervention methods, an explanatory summary diagram highlighting examples of PA delivery methods (e.g. consultations and pedometers) was given to all participants before the start of each FGD.

## 2.5. Analysis

Data obtained from the audio tapes were transcribed verbatim and then analysed using Nvivo 11 [32]. The approach used followed thematic content analysis [28] in line with the key aims of the study. Initial transcripts were read several times by authors TSA and SMA followed by open coding, grouping and categorizing data according to emerging themes. A coding scheme was then developed based on the major recurrent themes. Themes and sub-themes were cross-checked independently by two researchers (SA, and YA). The final themes and sub-themes were revised by a qualitative researcher (ZA) as a further measure of inter-rater reliability. Continuity of interpretation was ensured by one researcher (TSA), being responsible for the data collection and analysis. Transcripts were re-visited whenever conflicting interpretations of themes occurred.

## 2.6. Ethics

Prior to the commencement of each focus group, an explanation about the aim of the study was given along with details of what participation would entail. Written informed consent (in which participants' anonymity and confidentiality was assured) was provided by each participant. The study was approved by the Regional Research and Ethical Review Committee, Ministry of Health, Muscat, Oman.



**Table 1.** Topic guide.

Questions	
Opening	<ol style="list-style-type: none"> <li>1. To what extent does your work in the diabetes clinic involve addressing PA?</li> <li>2. How important do you think addressing PA is among the various health priorities in your routine diabetes clinic?</li> </ol>
Introductory	<ol style="list-style-type: none"> <li>3. Who are the health professionals currently providing PA information to people with diabetes in PHC – if any? How and in what format?</li> </ol>
Transition	<ol style="list-style-type: none"> <li>4. In relation to PA and T2D how comfortable are you with the following: <ul style="list-style-type: none"> <li>• Your ability to motivate and build self-confidence in patients for more PA</li> <li>• Your confidence to discuss and assess PA with patients attending diabetes clinics</li> <li>• Your ability to use behavior change techniques in patients for more PA</li> <li>• Your willingness to endorse PA along with the other health professionals involved in diabetes care in PHC?</li> </ul> </li> </ol>
Key	<ol style="list-style-type: none"> <li>5. What are the <ul style="list-style-type: none"> <li>• Barriers to PA promotion in diabetes management in PHC?</li> <li>• Opportunities to PA promotion in diabetes management in PHC?</li> </ul> </li> <li>6. Who can best be responsible of PA promotion in the current primary diabetes care?</li> <li>7. Based on reflections from literature, what are your thoughts on the following physical activity delivery methods: <ul style="list-style-type: none"> <li>• Physical activity consultations</li> <li>• Encouraging walking is one of the successful interventions for patients with diabetes, how can this be done?</li> <li>• Using technology to promote PA in patients with T2D</li> </ul> </li> <li>8. What could be useful components for an effective physical activity intervention in diabetes care?</li> <li>9. What resources/actions are needed to integrate PA in routine diabetes care in PHC?</li> </ol>
Ending	<ol style="list-style-type: none"> <li>10. Is there anything else you would like to add?</li> </ol>

### 3. Results

Twenty-nine HPs participated in the FGDs. All of them were involved in diabetes primary care across Oman. More than half ( $n = 17/29$ ) were doctors, of which three were additionally mid-level managers at central (ministerial), regional and departmental levels. The remaining participants were nurses ( $n = 5/29$ ) dieticians ( $n = 4/29$ ) or health educators ( $n = 3/29$ ). The majority of the participants were females ( $n = 20/29$ ).

Mean  $\pm$ SD years of work experience was  $8 \pm 4$  (range = 5–21) years with family physicians having the most years of experience within the group. However, irrespective of experience participants expressed that: a) PA is a health priority in routine diabetes clinics b) their contribution to address PA was limited and ranged from unremarkable to simple and general PA advice. Current PA promotion in diabetes care was described as “inadequate”, “inconsistent” and “unstructured”. Participants in the manager group expressed “no” confidence to discuss and assess PA with patients attending diabetes clinics, nor the ability to motivate, build self-confidence or use behaviour change techniques in patients for more PA. Participants of other groups used variable terms such as “less”, “not sure” and/or “somewhat sure” for the same. Nonetheless, they all highlighted their uncertainties in addressing PA in diabetes care. However, all groups expressed strong willingness to endorse PA along with the other health professionals involved in diabetes care in PHC.

#### 3.1. Barriers and opportunities to delivery of PA promotion in diabetes primary care

Three recurring themes related to barriers and opportunities to addressing PA in diabetes care were identified: the health care system, individual/intrapersonal (patient related) factors, and the environment/community.

##### 3.1.1. Health care system related barriers and opportunities to PA promotion

###### 3.1.1.1. Barriers

The main barriers identified across the groups were lack of PA supportive guidelines/standards, lack of resources including knowledge and skills for effective PA promotion, lack of facilities and overall limited space available for patient instruction.

*“Lack or poorly communicated physical activity guidelines and physical activity standards from the central (ministerial) level to the clinical (practical) levels” GP 6*

*“Am not sure about my knowledge and skills to support physical activity in patients with diabetes who may have multiple comorbidities and require structured physical activity advice, not just a general statement” Dietician 7*  
*“We don’t have a private place to sit with the patient” Dietician 1*

Other barriers that were cited included lack of educational materials, poor PA referrals, inadequate manpower, and diabetes clinics restricted to morning shifts. It was also noted that contrary to other primary care programs in Oman, PA is not integrated in the electronic primary health care information system limiting operationalization of PA services.

*“Physical activity is not considered in the primary health information system ‘ALSHIFA’ which makes it difficult to prescribe, follow up or evaluate” Family Physician 5.*

### 3.1.1.2. Opportunities

HPs were highly motivated to undertake PA promotion in diabetes care and willing to share the responsibilities of promoting PA with colleagues and patients. Implementing potential PA interventions in the health centre or the community was considered feasible. Additionally, the family physician group suggested gathering data from patients through research on perceptions and barriers to PA in order to identify potentially effective PA interventions.

*“Another thing which I believe in is the sharing, I really believe that we will not be able to do it alone, so we need everybody – and especially the patients – on-board” Family Physician 4*

*“We need more studies about perceptions and then about the barriers” Family Physician 6.*

## 3.1.2. Individual/interpersonal patient related barriers and opportunities to PA promotion

### 3.1.2.1. Barriers

Cultural norms of the acceptability of physical inactivity, sedentary jobs and use of domestic helpers were common barriers identified at the individual/interpersonal level. Females were perceived to be more prone to inactivity due to the cultural and societal restrictions. Terms such as “lazy”, “not willing”, “not motivated”, “no self-confidence” were used to describe inactive individuals.

*“In our culture (we don’t view physical activity as important?), taking medicine is enough, no need for physical activity” Family Physician 5*

*“Most of the Omani people are becoming sedentary at work” Dietician 5*

*“Our main problem is with the females, whom, they don’t have the time, they don’t have the place to do it, and . . . they have many social commitments”*  
 Manager 8

### 3.1.2.2. Opportunities

Participants stressed the importance of personalising PA interventions to patients as they may be at different levels of readiness to perform PA. Provision of the available social (family) support for PA was equally recommended by participants.

*“Patients’ readiness to carry out physical activity has to be evaluated”*  
 Dietician 2  
*“We need to emphasise group, family and friends ‘social’ support for physical activity, especially for the population in the diabetic clinic who are elderly”*  
 Manager 7

### 3.1.3. Environment/community related barriers and opportunities for PA promotion

#### 3.1.3.1. Barriers

All participants perceived a lack of PA facilities, particularly safe walking areas. Moreover, potential PA facilities within the community, in schools, are under-utilized by the public. Hence, participants felt that other PA stakeholders (sectors) were not supporting the Ministry of Health in PA promotion or implementing opportunities effectively. Although hot weather was mentioned, opportunities for indoor activities and PA in the early morning were also discussed.

*“We can’t utilize facilities in the community (school sports halls) for physical activities especially in the evening times when it’s closed”* Manager 3  
*“The other sectors should cooperate with us”* Manager 1  
*“Weather is a problem, but we can select a time where the weather is acceptable, like early mornings”* Manager 3

#### 3.1.3.2. Opportunities

The term “community mapping” was used by a senior manager who thought health workers should be aware of PA facilities within the geographical catchment areas of primary health care centres, in order to facilitate PA referrals when advised. Interestingly, available volunteering health groups were perceived to be under-utilized for PA promotion compared to other primary health care programs.

*“Community mapping for physical activity facilities (places and volunteering buddies) to inform health care providers is a good idea to improve PA referrals” Manager 6*

*“The Ministry of Health has utilized an active group of volunteers from the community to promote maternal and child health programs such as breastfeeding, I think we can utilize this group to promote physical activity too” GP 1*

### 3.2. Allocation of responsibilities within diabetes primary care

There was no consensus on who should take the responsibility of PA for adults with diabetes in PHC. Interestingly, due to uncertainties towards how to deal with PA promotion in the presence of comorbidities, dieticians did not feel that it could be their responsibility. However, other HPs thought that PA responsibilities should be allocated to the dieticians, as combining dietary advice with PA was perceived as appropriate. In fact the dieticians and health educators group went on to suggest new recruitments such as physiotherapists or trained PA nurses. Family physician doctors, on the other hand, suggested a team approach to promote PA in diabetes care, but since associating PHC services/programs to a focal point is the norm, they could then be the coordinators along with the dieticians to deliver PA services.

*“It is the dietician’s role to promote physical activity to patients with diabetes” GP 1*

*“Physiotherapist or a trained physical activity nurse” Dietician 3*

*“The entire team is responsible, but if we have to choose, I would say the doctor, ‘us’”. Family Physician 1*

### 3.3. Intervention components and required resources to address PA in diabetes primary care

Three main themes identified from a systematic review by Matthews et al. [20] were proposed for discussion: PA consultations (face to face, group or phone), PA sessions, and/or use of technology.

#### 3.3.1. PA consultations (face to face, group or phone)

Consultations were the most desirable intervention component although HPs did not feel skilled to undertake this. However, due to participants’ hesitancy on what to say, why, where and when, they all consistently recommended extensive training for the team involved in diabetes care.

Group consultations on the other hand were not welcomed in the current primary care setting due to associated complex arrangements (time, space, and logistics).



Except for the dietician group, use of pedometers was not recognized, but generally welcomed.

*“Physical activity consultation is one important part that we can integrate it in diabetes care” Family Physician 2*

*“It should be well-structured physical activity consultations. I think no one is well trained in this field” Family Physician 4*

*“I know that physical activity consultations linked to behaviour change is more effective, but we don’t know how to do it” GP 4*

*“Some people like face to face physical activity consultations which I think is better as not everyone has access to telephones, and don’t forget the cost of calling” Dietician 4*

*“I believe in our Omani culture face to face physical activity consultations would be better than phone or group or any other settings. People here like the patient-doctor interaction, especially in the initial visits” GP 6*

*“Group consultations are difficult to manage. I mean we need more space, time and other logistics” Dietician 4*

### 3.3.2. PA sessions

Participants thought that arranging services to promote PA, mainly walking sessions, supervised by the health centre was a good idea (and a precedent had been set with previous self-help groups and campaigns). However, such activities were not encouraged within the campus of the health centre due to the lack of safe and appropriate places to walk. Walking (individually, accompanied by somebody or in a group) was the most common type of PA viewed as acceptable, and was encouraged by all groups irrespective to disease condition or individuals’ age. Volunteers from the community were suggested by health educators in the dietician group to be linked to patients with diabetes who are willing to walk but lack social support to undertake this. The manager group felt that aerobic, resistance or Zumba classes could be arranged by staff from health centres for patients in a private gym, however it may not be sustainable.

*“I don’t feel bringing physical activity sessions to the health centre is a good idea. However, health educators may arrange and manage activities within the community” Family Physician 8*

*“We have these beautiful volunteers called the support group who are underutilised in PA promotion for diabetes care. We can use them to organise walkathons in the neighbourhoods or link them to walk patients. We also have the association like the elderly association of woman and the Omani Women Association who can do something similar to anti-smoking activities” Dietician 7*

*"I also think health centres can coordinate with nearby private facilities 'the gym' for possible aerobic, Zumba or resistance exercises for interested young patients perhaps, but then sustainability may be an issue for a larger group of patients" Manager 8*

### 3.3.3. Use of technology

Participants felt unsure of the benefits of technology for older individuals and those with limited education. The use of tablet, and PA promotional websites were favoured for young patients who were more likely to be familiar with technology. Telephone applications and use of smart devices such as "watches/bracelets", smart games such as Nintendo "Wii" consoles, and digital personal trainers were only mentioned by the family physician group, however cost was perceived as a drawback. Interestingly, use of a common telephone application "WhatsApp" to promote PA in diabetes care was commonly suggested:

*"Nowadays using WhatsApp is common [simple phone application], maybe we can introduce it to promote PA" Manager 6*

### 3.4. Required resources to promote PA for adults with type 2 diabetes

The most repeated prerequisite by all groups was establishing a supportive environment for PA promotion in the PHC setting, namely structural changes, for example a consultation room, in order to provide privacy to patients. Additionally, clear and well communicated guidelines across health workers and PA stakeholders were highly recommended. Most importantly, accredited PA training for all health care professions involved in diabetes care would need to be embedded and/or medicalized within PHC continuous professional development (CPD) training programs. Training for all was perceived as essential to overcome problems of staff shortages related to the uneven distribution of staff delivering primary diabetes care in health centres and their rapid turnover rate due to maternity leaves, retirement and transfers to other health centres. This was hoped to maintain and sustain service delivery for PA promotion.

Proposed training topics were variable including: PA definitions, guidelines, measurements, consultation skills including behaviour change techniques (goal setting and motivation), and follow up and monitoring tools.

*"Physical activity is not medicalized and hence there are no standard follow up, monitoring or evaluative tools for it in primary care" Family Physician 1*  
*"Prepare a physical activity friendly environment in the health centre. For example encourage health care workers to move (active meetings), ensure private consultation rooms and everyone in the health centre should participate" GP 1*

#### 4. Discussion

The current qualitative study is part of a formative piece of work to inform a PA intervention design in diabetes care in Oman. Similar questions were asked a population of T2D patients in a quantitative cross-sectional study reported elsewhere [9]. Consistent with ecological models of health behaviour [27], the responses from the multidisciplinary groups of this study reflect perceptions of the multidimensional influences on PA and the necessity for multilevel actions to address them. Given the sparse evidence available on appropriate PA interventions for Arab populations, this study provides a framework/model for the design and integration of PA in routine diabetes primary care that can be subsequently evaluated.

Three themes were identified: barriers related to the health care system, individual/interpersonal factors, and the environment/community. In the current study HPs expressed concerns relating to inconsistent and outdated PA guidelines. The recent Omani diabetes management guidelines on PA are based on outdated evidence and therefore require revision as the last production was in 2015 [12]. Guidance on PA recommendations for adults with diabetes has been described in several studies [33, 34], however further details for implementation are required. Since it is a norm to have a representative body for health programs in Oman Ministry of Health, assigning one for implementing PA services would be ideal to execute PA guidelines (at least 150 min of moderate to vigorous physical activity or 75 min of vigorous PA/week or an equivalent combination of moderate- and vigorous-intensity PA achieving at least 600 MET-minutes per week [35] across HPs involved in diabetes care. Additionally, other constraints related to availability of consultation rooms, educational materials, manpower, timing of diabetes clinics, and integration of PA in the current health information system need to be developed and included in an executive PA promotion action plan.

At the individual/interpersonal patient level, socio-cultural barriers, particularly the restrictions noted for women such as limited safe PA facilities and walking tracks, are reported from other Arab communities in the Middle East [36] and the USA [37, 38]. Hence, PA promotion should be targeted to address females' inactivity levels through widening available opportunities.

Perceived barriers which were related to the environment/community were similar to findings of other studies, namely hot weather and limited PA facilities [39]. PA interventions should therefore consider walking tracks and special culturally appropriate exercise facilities and services e.g. women only exercise classes.

It was agreed that in an ideal health care setting all HPs should have the responsibility and skills to effectively deliver PA information. In fact PA endorsement by health workers in PHC settings is reported as one of the seven



investments that work in promoting PA [40]. Research suggests that patients consider their GP to be the most trusted source of PA advice [41]. However, despite mixed views on responsibilities for PA promotion, the tendency was for dietitians to be the favoured sources for both diet and PA promotion by study participants in the current local PHC setting. Patients with T2D have previously reported finding it easier to manage dietary changes when in combination with PA [42].

Face to face consultations were valued over telephone and/or group consultations by participants, especially for initial consultations. This could be justified by the cultural preferences to discuss health issues in private; especially that females in Arabic speaking countries namely Oman may not feel comfortable to discuss their weight, health and PA behaviour in group settings [3]. Additionally telephone consultations may not be accepted given the time and cost associated with using phone services. However, since evidence showed that telephone counselling is an effective method of increasing levels of PA in women with T2D in Western countries, such as the USA [43], it is wise to consider its application in future PA interventions.

While the current study identified barriers to PA promotion by HPs, another complimentary formative study showed that lack of willpower was the frequently reported barrier to performing PA by patients with T2D [44]. Hence, the use of motivational tools such as pedometers was welcomed by all HPs in the current study. Pedometers have been shown to be helpful in increasing PA levels and in improving metabolic parameters in patients with diabetes in several previous studies [24, 45]. An advantage with pedometers is their ability to increase the motivation to be more active and less sedentary on a daily basis, therefore future PA interventions should include pedometer use.

Furthermore, effectiveness of community involvement in PA promotion has consistently showed positive outcomes [46, 47]. Referrals to an organized community PA resource, such as walking buddies (community volunteers), and neighbourhood gym may all be adopted.

Finally, irrespective of who the PA focal point is in PHC. An intense training to health care providers on PA is required including benefits, definitions, recommendations, type, measurements, dealing with multiple comorbidities and evaluation. To ensure sustainability, training workshops were advised within primary health care CPD activities. More importantly, behaviour change training was highly recommended.

#### 4.1. Study limitations

It should be noted that the facilitator (TSA) had worked with all study participants for several years, and thus, familiarity with all participants may have introduced

bias, with participants providing socially desirable responses. However, efforts to minimize potential bias were taken through firm FGDs facilitation skills and data collection [28]. Additionally, we are unable to assess how representative the views reported in this study are of those of the wider population of HPs working in diabetes care within PHC across the different regions of Oman. All participants have a very good working knowledge of English, but their responses may have been limited since the interviews were not conducted in their mother tongue, Arabic. Another potential limitation is that sitting time and sedentary behaviour were not included as specific topics for discussion within the focus groups. Prolonged sitting time has been identified as an independent risk factor for diabetes, cardiovascular disease, and all-cause mortality [48]. Hence, further studies are required to explore sitting time and sedentary behaviour in adults with T2D in Oman.

## 5. Conclusion

This study highlighted key perceived barriers and opportunities for a PA program for patients with T2D. Despite clinical, individual, and environmental factors that could limit PA behaviour, opportunities do exist within the positive spirit of health care workers for PA promotion. This study proposed an intervention with multiple components across clinical and community contexts. In the presence of various diabetes primary care providers, dieticians were considered best to provide face to face PA consultations linked to behaviour change techniques. Participants were excited to introduce “WhatsApp” and pedometers as follow-up, and monitoring PA tools. Additional community support was recommended from the current available resources (volunteers/PA facilities). To initiate and sustain PA promotion, a training program needs to be institutionalized within the current CPD activities for all health care providers in primary care.

## Declarations

### Author contribution statement

Thamra Al Ghafri, Samiya Al-balushi, Zakiya Al-busaidi, Yahya Alfarsi: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Saud Alharthi: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Elaine Bannerman, Angela Craigie: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

Annie S. Anderson: Conceived and designed the experiments; Performed the experiments; Wrote the paper.

### Competing interest statement

The authors declare no conflict of interest.

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### Additional information

Data associated with this study (transcripts of the focus group discussions) is available on request and approval from the Oman Ministry of Health.

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## Appendix 5.2: Participants' information sheet and consent

### Focus Group Participants Information Sheet

I am Dr. Thamra Al-Ghafri, Director of Planning in Muscat region, Ministry of Health. I am doing research on physical activity (PA) among Omani patients with type 2 diabetes mellitus (T2D). I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me.

Your opinion is vital to our research because you are a senior physician conducting diabetic clinics in your respected health center (place of work). What you think will inform an intervention design to integrate PA in diabetes care in primary health care.

It's important to take the time you need in order to provide both spontaneous and considered opinions on PA as per the questions asked by the group leader: Dr. Thamra Al-Ghafri.

If you want to revise your opinion at any time inform the group leader before the focus group discussion ends. If at any time you do not understand one of the ideas presented, please ask for clarification- you are an important part of this research.

We believe this topic is important because and as you know, managing diabetes is a challenge. We want your support in exploring ways to integrate PA as a recognized national PHC program.

You will be part in a discussion with at least 4 other persons with similar experiences. The group discussion will start with me, making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the PA among T2D patients attending PHC and give you time to share your knowledge.



These are the types of questions we will ask:

1. To what extent does your work in diabetes clinic involve addressing PA?
2. How important do you think addressing PA is among the various health priorities in your diabetes clinic?
3. Who are the health professionals currently providing PA information to people with diabetes in PHC?
4. What are the barriers and opportunities to addressing PA in diabetes management?
5. In relation to PA and type 2 diabetes how comfortable are you with the following:
  - Your confidence to discuss PA with patients attending diabetes clinics
  - Your ability to motivate and build self-confidence in patients for more PA
  - Your willingness to endorse PA along with the other health professionals involved in diabetes care in PHC?
6. Based on these reflections, what are your thoughts on the following physical activity delivery methods:
  - Physical activity consultations
  - Encouraging walking by patients or other exercises
  - Using technology to promote PA

7. What resources and trainings are needed to integrate PA in routine diabetes care in PHC?

The discussion will take place in Directorate General of Health Services (DGHS), Muscat facilities, and no one else but the people who take part in the discussion and the investigating team will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The recordings will be kept with the Dr, Thamra in a secured place. The information recorded is confidential, and no one else except the PI will have access to the recordings. The tapes will be destroyed after 5 year from the date of reporting the results of this study.

There will be no direct benefit to you, but your participation is likely to help us find out more about how to integrate PA in the management of diabetes within PHC setting.

You will not be provided any incentive to take part in the research. However, we will give you humble gifts and an appreciation letter for your time.

We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the discussion at any time that you wish without your job being affected. I will give you an opportunity at the end of the discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.

This proposal has been reviewed and approved by the Research and Ethical Review and Approve Committee, in Ministry of Health of Oman whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the committee, contact department of research and studies at 24601161.

Beyond this focus group, we will not contact you for additional or follow up information. We want you to be very clear about your agreement to participate and that your participation is entirely voluntary. For that reason, you are requested to sign the attached consent form.

If you have any questions you may contact me by telephone or email.

Researcher: Dr.Thamra Al-Ghafri

Telephone number: 99376455

Email:thamra74@yahoo.com

## Focus Group Participants Consent Form

By signing this consent form, you are not waiving your legal rights or jeopardizing your professional responsibilities.

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I have read the information presented in the participants information sheet about the study being conducted by Dr. Thamra Al-Ghafri. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I wanted. I am aware that I may withdraw from the study without penalty at any time.

I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact the Quality Section in the Directorate General of Health Services, Muscat at 24782105.

With full knowledge of all foregoing, I consent voluntarily to be a participant in this discussion.

Name of Participant\_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date (day/month/year) \_\_\_\_\_

## Appendix 6.1: Published study protocol

Alghafri et al. *BMC Public Health* (2017) 17:28  
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BMC Public Health

### STUDY PROTOCOL

### Open Access



# Study protocol for “MOVEdiabetes”: a trial to promote physical activity for adults with type 2 diabetes in primary health care in Oman

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### Abstract

**Background:** Benefits of physical activity in the management of diabetes are well documented. However, evidence on the effectiveness of interventions integrating physical activity in diabetes care is sparse especially in the countries of the Gulf Cooperation Council. The results from this study will increase our understanding of the use of multi-component interventions aimed at increasing physical activity levels in inactive adults with type 2 diabetes in primary health care in Oman.

**Methods/design:** The study is a one year 1:1 cluster randomized controlled trial of the MOVEdiabetes programme (intervention) versus usual care in eight primary health care centres in Oman. The MOVEdiabetes programme utilizes face to face physical activity consultations promoting 150 min of moderate to vigorous physical activity per week ( $\geq 600$  MET-mins/week), pedometers to self-monitor step counts and monthly telephone WhatsApp messages for follow up support. Inactive adults with type 2 diabetes and no contraindication to physical activity will be recruited over a two months period, and followed up for 12 months. To demonstrate a 50% between group difference in physical activity levels (MET-mins/week) over 12 months, (at a power of 80%, and significance level of 5%), 128 participants would be required to complete the study (64 in each arm). Based on a drop-out rate of 20%, 154 participants would require to be recruited (77 in each arm). Assuming a recruitment rate of 70%, 220 potential eligible participants would need to be approached. The primary outcome is change in levels of physical activity measured by the Global Physical Activity Questionnaire. In addition, accelerometers will be used in a sub group to objectively assess physical activity. Secondary outcomes include changes in metabolic and cardiovascular biomarkers, change in self-reported health, social support, self-efficacy for physical activity, and perceived acceptability of the program. All intervention delivery and support costs will be monitored.

**Discussion:** This study will contribute to the evidence on the feasibility, cultural acceptability and efficacy of interventional approaches for increasing physical activity in primary care for persons with type 2 diabetes in Oman.

**Trial registration:** International Standard Randomised Controlled Trials No: ISRCTN14425284. Registered 12 April 2016.

**Keywords:** Physical activity, Type 2 diabetes, Primary health care, MOVEdiabetes, Intervention, Oman

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## Background

The International Diabetes Federation (IDF) estimates that 8.3% of people globally have diabetes (382 million), 90% of which is type 2 diabetes (T2D) and the numbers affected are expected to increase by 55% (to 592 million) by 2035 [1]. In countries of the Middle East and North Africa (MENA) region, the impact of diabetes is a major concern, especially in the Arab Gulf countries which have the highest prevalence of diabetes in the world [2].

Oman, similar to the other high income countries of the Gulf Cooperation Council (GCC) [3], has gone through rapid economic development leading to high energy dense diets and sedentary lifestyles [4]. Diabetes prevalence in Oman increased from 8.3% in 1991 to 11.6% in 2000 and 12.3% in 2008 and recent estimates are in the order of 14.2% [1, 5]. Oman and other GCC countries are facing similar challenges related to management of diabetes and the IDF has estimated that the MENA will have a 96% increase in the number of people with diabetes by 2035 [1, 6].

The evidence around the impact of physical activity (PA) on both the prevention and management of T2D is well documented [7, 8]. To reach the clinical benefits of PA, the World Health Organization (WHO) recommends at least 150 min of moderate-intensity PA OR 75 min of vigorous-intensity PA per week, which equates to an equivalent combination of moderate- and vigorous-intensity PA achieving at least 600 MET-min/week. Meeting physical activity recommendations has been shown to increase insulin sensitivity, lower blood sugar levels, reduce body fat and improve physical condition [9].

Based on the best-available data derived from subjective PA measurement tools (e.g. Global Physical Activity Questionnaire (GPAQ), International Physical Activity Questionnaire (IPAQ-Short) and locally developed questionnaires), the population estimate for adults meeting WHO PA recommendations in Arab countries is around 40% for men and 27% for women [10]. A regional study in Sur (north-east coast of Oman), using GPAQ, showed the highest levels of physical inactivity were in leisure time (55%) and the median sitting time was about two hours/day [11].

While in western countries (USA) it has been reported that over 60% of patients with T2D don't meet the recommended levels of PA [12], consolidated evidence demonstrating PA levels in populations with T2D in Arabic countries is scarce. In Oman, the national health survey 2008 [5] reported that 15% of adults with T2D were physically active based on international recommendations (150 min per week) while in Lebanon only 10% of adults with T2D were reported to reach the recommended levels of PA versus 23% with inadequate levels [13].

Evidence on the best PA interventions for patients with T2D in primary care worldwide is unclear. Interventions differed by settings (primary care vs community), methods (consultations vs exercise sessions), and duration (short-

term vs long-term). PA consultations and exercise sessions linked to theories of behaviour change seem to significantly improve activity levels for patients with T2D [14]. Additionally, technology bound interventions and the use of motivational tools, such as pedometers, have been consistently recommended in interventional studies [15, 16]. Walking interventions have also shown significant positive effects in lowering glycated haemoglobin levels (HbA1c) and improved diabetes health outcomes [17]. However, there is still a gap in the evidence on the best methods, intervention components and intervention intensity that would be most effective in increasing long-term PA in the primary care setting for persons with T2D [14, 18].

Almost all interventions have been carried out in non-Arabic speaking countries hence, evidence for culturally sensitive PA interventions is warranted. Based on these gaps in knowledge, this study aims to explore uncertainties about translating existing evidence from western settings to local clinical settings in Oman whilst taking account of cultural boundaries.

## Methods

### Primary objective

The primary objective is to evaluate the impact of a multi-component intervention (MOVEdiabetes) which aims to achieve 150 min of moderate to vigorous physical activity/week ( $\geq 600$  MET-mins/week) in inactive adults with T2D attending primary health care facilities in Oman.

### Secondary objectives

The secondary objectives of the study are:

- Estimate the impact of MOVEdiabetes programme on cardio-metabolic risk factors.
- To evaluate the impact of utilizing a common telephone application, WhatsApp, as an intervention reminder and follow up tool.
- To examine the acceptability of the intervention (content, delivery and aims) to the participants and project officers (health care providers).
- To assess the practical issues (including costs) that could challenge or assist programme delivery and roll out.

### Study design/location/recruitment

#### Randomisation

The study is a 1 year 1:1 cluster randomized controlled trial of the MOVEdiabetes intervention versus usual care. A cluster randomization design was used to minimize between group contamination by having the two groups (intervention and comparison) from independent health centres. Group allocation will be generated using a random numbers table generated in SPSS v21 by an independent statistician in Oman Ministry of Health. All health centres

(8) will be randomised to deliver either the intervention ( $n = 4$ ) or usual care ( $n = 4$ ). Health centres will be informed of their allocation verbally by the project investigator and will receive an envelope containing invitation letter and project materials.

### Recruitment

To ensure that intervention delivery is institutionalized within routine diabetes care in the selected health centres, three project officers will be recruited at each side ( $n = 24$ ) from existing health care providers (doctors/nurses/dieticians/health educators). Project officers will receive study specific training on the recruitment procedures, screening the participants, recording outcome measurements, and delivering the MOVEdiabetes intervention in intervention health centres (IHC).

All eligible patients attending their routine diabetes clinics in the selected health centers will be informed about the study by the project officers and invited to participate in the study. Interested patients will be screened for physical inactivity using the Scottish Physical Activity Screening Questionnaire (Scot-PASQ) (<http://www.paha.org.uk/Resource/scottish-physical-activity-screening-question-scot-pasq>).

### Inclusion criteria

- Adults aged 18 to 60 years
- Diagnosed with type 2 diabetes
- Attending health centres for at least six months previously for diabetes care
- Assessed by project officer as having inactive behaviour
- No contraindication to physical activity
- Able to speak and read Arabic
- Willing and able to provide written informed consent to the study

### Exclusion criteria

Patients with:

- Type 1 diabetes
- A history of myocardial infarction in the previous 6 months
- A serum creatinine  $>140$  mmol/L (from previous recorded readings in the electronic health information system)
- Diabetic foot ulcers or at high risk of ulcer (severe peripheral neuropathy)
- Repeated hypoglycaemia or severe hypoglycaemia in previous 12 months
- No internet access for WhatsApp
- Physical activity  $>150$  min per week

### Recruitment

Recruitment will take place over a 2 month period (8 weeks). Inactive patients fulfilling the inclusion criteria will be provided with a participant information sheet

about the study by the project officers and a subset of patients (40%) showing interest will be offered an accelerometer to be worn for a week prior to their measurement visits to validate the GPAQ results and as a primary measurement tool to evaluate the change in METS-mins/week, sitting time and step counts. Initially all participants ( $n = 220$ ) will be offered accelerometers until the required numbers are reached in all eight health center ( $n = 11$ ). Subsequently, an appointment will be given to all potential participants to attend a wellbeing clinic for baseline measures, linked to their diabetes clinic, within a week. A telephone call will be made to all willing participants to remind them of their appointment and ensure activation of the accelerometer.

At the baseline visit the project officers will seek written informed consent and log any eligible individuals who decline participation (Fig. 1).

Recruitment will be monitored fortnightly and efforts to reduce loss to follow-up will be made. Participants not attending their appointment will be called to consider rescheduling their appointments. Reasonable travel costs will be reimbursed.

### Measures/assessment instruments

Baseline and follow-up data will be collected face to face and from the electronic health information system in the health centre (AlShifa system) (Table 1).

### Intervention

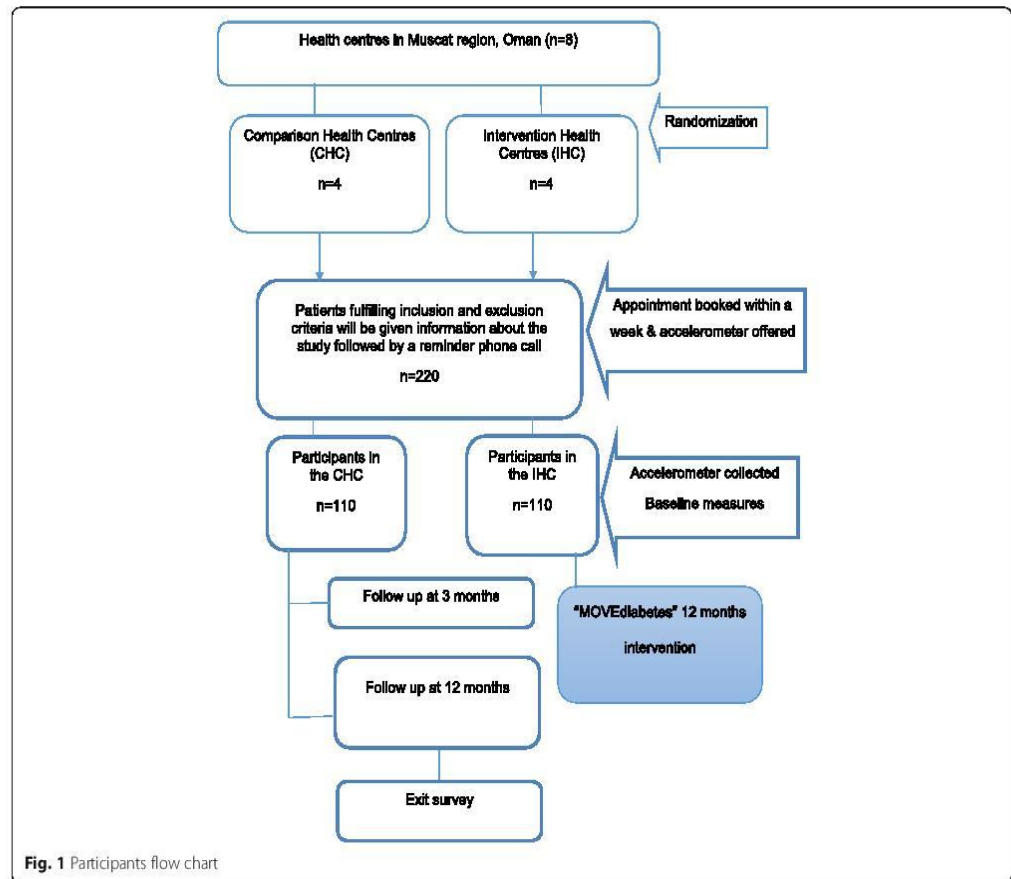
The intervention group will receive the “MOVEdiabetes” personalised PA consultations, pedometer (YAMAX Digi-walker SW-200) to measure weekly step counts and WhatsApp messages (Table 2).

### Face to face PA consultations

Recruited participants will be offered individual consultations (maximum 20 min) by the trained project officers on 3 occasions (0, 4 and 8 weeks) (Table 2). This will be undertaken a week after completing 7 days of accelerometer wear in the selected participants (accelerometer group) mostly in week 0 and 8.

The consultations aims to encourage participants towards achieving 150 min of PA per week ( $\geq 6000$  MET-mins/week) at 12 months which has been demonstrated to be clinically effective in diabetes management. It is estimated that a step count of not less than 6000–7000 per day is required to achieve this goal [19]. Participants will be encouraged to increase their step counts gradually to achieve this goal.

PA programme design based on a theory and the behavior change techniques is widely proven to be effective [20, 21]. The theoretical framework underpinning the intervention in this study is the Health Belief Model, the Stages of Change Model and the



**Fig. 1** Participants flow chart

Social Cognitive Theory [7]. The MOVEdiabetes personalised, multiple contact, intervention programme will also be based on several behavior change techniques based on the Abraham and Michie taxonomy [22] which includes (a) goal-setting for PA; (b) self-monitoring to achieve these goals; (c) frequent contact to provide accountability and sustain focus; (d) use of problem-solving to address goals and potential barriers to achieving them; and (e) emphasis on managing individual high-risk situations.

#### Pedometer

Participants will be given a pedometer (YAMAX Digi-walker SW-200) at their baseline visit. Instructions on how to use the pedometer, how to record their daily steps and how to set daily step goals will be discussed by the project officers. Participants will be asked to set individual goals and fill in a daily step count to be submitted to the project officers in their respective health centres over a three month period and at 12 months.

#### WhatsApp

Participants receiving the intervention will be asked to open and share a telephone WhatsApp application with the project officers in their health centre to facilitate the reporting of their step counts and get support during the intervention period. Additionally, monthly standardized physical activity motivational messages will be delivered through this telephone application. Participants are also invited to join a WhatsApp peer support group to share their experiences with other MOVEdiabetes participants.

#### Process evaluation

Programme acceptability will be explored post-intervention via a brief exit questionnaire with all project officers and 50% of intervention participants randomly selected by random number tables generated in SPSSv21 by the principal investigator. The questionnaire will explore the extent initial expectations and motivations regarding the programme were met, engagement with the programme, acceptability (content, delivery and aims) of



**Table 1** Outcome measures

Table 1. Outcome measures	Tool	When	
		Intervention	Comparison
Primary outcome			
GPAQ-MET-mins/week	Questionnaire	B, 3 F, 12 F	B, 3 F, 12 F
Accelerometer (activePAL™)	Reporting step count, MET-min/week, and sitting time	B, 3 F, 12 F	B, 3 F, 12 F
Pedometer (YAMAX Digi-walker SW-200)	Reporting step counts	B, 3 F, 12 F	-
Secondary outcomes			
Socio-demographic data	Questionnaire	B	B
Height (m)	Stadiometer	B	B
Body weight (Kg)	Calibrated scales	B, 3 F, 12 F	B, 3 F, 12 F
Waist circumference (cm)	Tape measure	B, 3 F, 12 F	B, 3 F, 12 F
Lipid profile (mmol/l)	Blood test (venous fasted sample)	B, 3 F, 12 F	B, 3 F, 12 F
Blood pressure (mmHg)	Sphygmomanometer	B, 3 F, 12 F	B, 3 F, 12 F
<sup>a</sup> HbA1c (%)	Blood test (fasted sample)	B, 3 F, 12 F	B, 3 F, 12 F
Self-assessed general health	Questionnaire	B, 3 F, 12 F	B, 3 F, 12 F
Self-efficacy for PA	Questionnaire	B, 3 F, 12 F	B, 3 F, 12 F
Social support for exercise	Questionnaire	B, 3 F, 12 F	B, 3 F, 12 F
Cost analysis (description)	Detailed cost description	12 F	-
Exit survey	Questionnaire (participants and project officers)	12 F	-

(B = baseline; 3 F = 3 month follow-up, 12 F = 12 month follow-up)

<sup>a</sup>while blood collection for HbA1c at 12 month is mandatory, it is only done at baseline and 3 month if missing from the electronic health information system or recorded within more than 4 months prior to the measurement visits

the approach e.g. if the intervention was tailored to be appropriate and realistic to the individual's lifestyle, and elements of overall rating of the project including factors influencing willingness and ability to comply with the programme advice.

### Assessment of fidelity to protocol

#### Managerial:

- The project group will have monthly meetings to discuss issues regarding the physical activity consultations, and measurements to ensure their compliance to intervention protocol.
- A telephone application (WhatsApp) will be used throughout the study period by project officers and the PI to manage the daily logistics and administrative queries.

- Attendance sheets will be reviewed and discussed.
- Qualitative:
- Audio-recording and transcription of 5 PA consultations randomly selected by random number tables generated in SPSSv21.
  - Crosschecking of 10% of PA consultation notes randomly selected by a recruited external assessor.
- Evaluative:
- The brief exit survey will include questions on adherence to the protocol specifically for project officers.

### Sample size

To demonstrate a 50% between group difference in physical activity levels (MET-mins/week) over 12 months, to be detected at a power of 80%, and significance level of 5%, 128 participants would be required to complete

**Table 2** MOVEdiabetes intervention components

Intervention visits	Weeks												
	0 <sup>a</sup>	4	8 <sup>a</sup>	12	16	20	24	28	32	36	40	44	48
Face to face physical activity consultations	→	↔	←										
Weekly WhatsApp step count	→	↔	↔										←
Monthly WhatsApp messages	→	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	←

<sup>a</sup>After 7 days of PA recordings from accelerometers in the selected sub groups

the study (64 in each arm). Based on a drop-out rate of 20%, 154 participants would require to be recruited (77 in each arm). Assuming a recruitment rate of 70%, 220 potential eligible participants would need to be approached.

### Statistical analysis

The initial quantitative analysis will be an intention-to-treat analysis between the two cluster groups (intervention versus control) but secondary analyses will explore the effect of actual treatment received. The initial analysis will involve standard two-sample comparisons (parametric or nonparametric as dictated by the distribution of the data) looking at effect sizes at 3 and 12 months using t-tests or Mann-Whitney tests for differences in means as well as repeated measures or chi squared tests for differences in proportions. Differences by health centre will be explored and, if statistically significant will be entered in a mixed model as a random effect. The balance of characteristics between treatment and control arms will be tabulated and if differences are noted, adjustment will be made for these in linear regression models.

Results from the open-ended questions in the exit survey will be analysed thematically to identify the perceived acceptability of the intervention (content, delivery and aims) to the participants and project officers (health care providers).

### Discussion/rationale for current trial

Adults with T2D are known to have multiple comorbidities and are generally less active than the general population [23]. Behaviour change programmes targeting vulnerable populations are more effective than those targeting the population at large [24]. Additionally, use of technology namely phone applications (WhatsApp in this study) is a positive followup and monitoring tool to promote longterm PA [15].

PA on a regular basis improves metabolic, blood lipid profile control and quality of life [7]. Additionally, several studies have shown preventive effects of physical activity in individuals with T2D in lowering the risk of cardiovascular disease and premature death [25].

One advantage of the primary care setting in this study is its familiarity to potential participants. More importantly, when interventions are delivered in a clinical setting, desired outcomes are enhanced because of better medical endorsement and feelings of the intervention being an integrated part of care [26].

It is hoped that results from this study will enhance the evidence base for effective routes to increasing physical activity in inactive adults with T2D; by assessing the impact of MOVEdiabetes intervention on PA levels; providing a platform (feasibility evidence) for the MOVEdiabetes intervention to be initiated in routine primary care clinics; increase understanding of participant

engagement, barriers, opportunities; and examining cost related issues about intervention procedures in this clinical and cultural setting.

This study is of direct relevance to the ministry of health of Oman and has the potential to significantly enhance current government action on promoting physical activity. The study will equally assist in formulation and implementation of suitable plans of the National Health Policy Priorities: "5. To promote the health awareness of the community and establish a culture of healthy lifestyles" [27].

### Conclusion

It is hoped that this research will help to inform current policies and practices of the Omani Ministry of Health for the use of a culturally acceptable physical activity interventions as an integral part of care for clients with T2D within the primary health care setting.

### Abbreviations

BMI: Body Mass Index; CHC: Comparison Health Centre; GCC: Gulf Cooperation Council; GPAQ: Global Physical Activity Questionnaire; HbA1c: Glycated haemoglobin; IDF: International Diabetes Federation; IHC: Intervention health centre; IPAQ: International Physical Activity Questionnaire; MENA: Middle East and North Africa; PA: Physical activity; Scot-PASQ: Scottish Physical Activity Screening Questionnaire; WHO: World Health Organization

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### Availability of data and materials

Data generated from this study is not publicly available as this requires approval from Oman Ministry of Health, however it is available from the corresponding author on reasonable request.

### Authors' contributions

TS is the principal investigator in charge of the project. SM, YA, AC, MM, and ASA have all been involved in designing the intervention. ASA provided the overall supervision of the project (conception of idea, research design, report writing, interpretation of results, and critical reviewing). TS prepared the initial draft of the manuscript and all other authors have contributed. All authors have critically reviewed and approved the final version of the manuscript.

### Competing interests

The authors declare that they have no competing interests.

### Consent for publication

Not applicable.

### Ethics approval and consent to participate

Ethical approval is obtained from the Omani Research and Ethical Review and Approve Committee in the Ministry of Health and reciprocally approved in University of Dundee. All eligible participants will be invited to the study

in their respected health centres (with a spouse, or other support member) to provide informed consent before recording the baseline measures. Copies of all ethical approval and funding approval is forwarded to BMC Series Editorial@biomedcentral.com.

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## Appendix 6.2: Accelerometer wear protocol



### **Accelerometer wear protocol for participant of the “MOVEdiabetes” study**

#### **General instructions to the participants**

Please wear the monitor every day for 7 days removing it on the morning of day 8.

Please wear the Thigh Monitor continuously (24 hours/day).

The Thigh Monitor can be worn during sleep and is water resistant (to 1m) so you can wear it whilst showering and bathing but please do not wear it in the swimming pool in case it falls off.

The adhesive patch that sticks the Thigh Monitor to your skin may last up to 7 days but to avoid skin irritation to may want to change the adhesive patch

Note: The Thigh Monitor will emit a green flash every 6 seconds. This is an indication that it is working and recording data.

#### **Instructions on how to remove the device**

Remove the Thigh Monitor from your thigh (note that this may cause some slight discomfort) and peel the adhesive patch off the Thigh Monitor. The monitor is covered in a waterproof sleeve and wrapped in one adhesive patch—please make sure that these remain on the monitor when you do this.

With an alcohol prep pad provided in your Activity Monitor Pack, thoroughly wipe down the monitor and the area of your leg where the Thigh Monitor was attached.

Position the Thigh Monitor in the same spot as previously on your thigh (or on the other thigh if you have had a slight irritation), ensuring that the stick man on the front of the Thigh Monitor is standing up (head facing upwards).

Peel the backing off an adhesive patch and place it over the Thigh Monitor. Press the patch onto your skin, peel back the top layer of the patch and smooth out the air bubbles and wrinkles as much as possible to ensure that the Thigh Monitor is firmly secured to your thigh.

### **What else you need to do?**

It is important that you fill in the Daily Log on the following pages every day for the 7 days while you are wearing the monitor.

This helps us to look specifically at the data from when you were awake.

### **How to fill in the daily activPAL log**

The log is divided into 7 days. Please complete each question for all of the seven days. Please try and be as accurate as possible—record the exact times if you can, or at least to the nearest 5 minutes of your estimated times.

Start by writing the date in the top row. Then record the time that you woke up and the time that you actually got out of bed (these times may be the same for some days). We ask for these two times because people sometimes spend time in bed before going to sleep or getting up and we are interested in distinguishing between actual sleeping time and time in bed before sleep or once awake.

If you remove the device for longer than 10minutes during the day please note down the time that you removed the device, the time that you re-attached it and the reason why you removed the device. This is particularly important as we cannot tell from the data if you are lying down or whether you have removed the device and are just not wearing it (the data looks the same when we look at it).

Then record what time you got into bed to go to sleep and the time that you actually went to sleep time. (i.e., the estimated time that you fell to sleep not the time that you got into bed). This is important as the monitor cannot tell the difference between asleep and awake times, and we are only interested in your activity while you are awake.

Please record your sleep time first thing in the morning when you wake up along with your wake time.

There is also a space for you to make comments. It is useful for us to know if you have had any skin irritations, accidentally worn the monitor upside down or any other information that you think we should know.

Once you have completed your 7 days of wear please return this log along with your thigh monitor to our research team in the envelope provided by our research tea

Day and Date	Time woke up	Time got out of bed	Did you remove your monitor for >10 mins today?  Yes/no	If removed, record time of removal and reason why  Time off & Time on  Reason:	Time got into bed	Time went to sleep	Other comments/ side effects
Day 1  Date:							
Day 2  Date:							
Day 3  Date:							
Day 4  Date:							
Day 5  Date:							

Day 6 Date:							
Day 7 Date:							
Day 7 Date:							



## Appendix 6.3: The ethical approval for the "MOVEdiabetes" study

Sultanate of Oman  
Ministry of Health  
Directorate General of Planning  
and Studies



سلطنة عُمان  
وزارة الصحة  
المديرية العامة للتخطيط  
والدراسات

Ref. : MH/DGP/R&S/PROPOSAL\_ APPROVED/1/2016

Date : 05.1.2016

الرقم :  
التاريخ :  
الموافق :

Dr. Thamra Al-Ghafri  
Principal Investigator

Study Title: "“MOVEdiabetes” A Trial to Promote Physical Activity for Adults with Type 2 Diabetes in Primary Health Care in Oman ".

After compliments

We are pleased to inform you that your research proposal " “MOVEdiabetes” A Trial to Promote Physical Activity for Adults with Type 2 Diabetes in Primary Health Care in Oman " has been approved by Research and Ethical Review & Approve Committee, Ministry of Health.

Regards,

٢٠١٦/١/٥



Dr. Ahmed Mohamed Al Qasbi  
Director General of Planning and Studies  
Chairman, Research and Ethical Review and Approve Committee  
Ministry of Health, Sultanate of Oman.

Cc  
Day file



### University of Dundee Research Ethics Committee

University of Dundee,  
Dundee,  
DD1 4HN.

19 January 2016

Dear Thamra

**Application Number: UREC 16006**

**Title: "MOVEDiabetes" a trial to promote physical activity for adults with type 2 diabetes in primary health care in Oman**

I am writing to you to advise you that your ethics application has been reviewed and approved by the University of Dundee Research Ethics Committee.

Approval is valid for three years from the date of this letter. Should your study continue beyond this point, please request a renewal of the approval.



Any changes to the approved documentation (e.g., study protocol, information sheet, consent form), must be approved by UREC.

Yours sincerely,

A handwritten signature in black ink, reading "A. Schloerscheidt", is shown within a rectangular box.

Dr Astrid Schloerscheidt  
Chair, University of Dundee Research Ethics Committee

**Appendix 6.4: The “MOVEdiabetes” participants’ information sheets in both English and Arabic languages for the intervention group**



**“MOVEdiabetes”**

A Trial to Promote Physical Activity for Adults with Type 2 Diabetes in Primary Health Care in Oman

**INFORMATION ABOUT THIS STUDY FOR PARTICIPANTS**

MOVEdiabetes Participant Information Sheet (Intervention), V4.0,  
27th November 2015

## **PART 1: BACKGROUND TO THE STUDY**

Diabetes is a major health problem in Oman. We also know that many people are very sedentary. Increasing to 150 minutes per week of moderate or vigorous activity can have many health benefits. These include improvements in blood tests, lower blood pressure, increased muscle strength and lower levels of depression. People who exercise report feeling better and an improved quality of life.

### **Why am I being invited to take part in this study?**

This study is being carried out with adults who have Type 2 diabetes and who have been followed up in a health centre diabetes clinic for 6 months or more. We want to see whether we can help increase physical activity levels which will reflect positively on health by introducing physical activity intervention. Different health centres have different groups within the study.

### **Why should I read this leaflet?**

Before you decide whether or not you would like to take part in the study, it is important that you understand why we are doing it, and what it involves. Please read this leaflet carefully. If you have any questions, you should contact Dr.Thamra on 94170961. Dr.Thamra will try to answer any questions that you have and give you any further information you may need. You may also want to discuss it with your family and friends. You do not have to make an immediate decision about taking part in the study.

### **Where is the study being carried out?**

This study is being carried out in health centers in Seeb. The study is being led by Ministry of Health, together with Sultan Qaboos University and University of Dundee (UK).

## PART 2: WHAT WILL I HAVE TO DO?

If you agree to take part we will ask you to attend four visits over a 12 month period. The visits will be to take some measurements, routine diabetes blood tests and to ask you some questions about exercise levels and overall health. You will receive 20 minutes physical activity consultations and be given a pedometer. You will also be asked to share a WhatsApp telephone application with the research officer in your respected health centre to receive monthly message updates on physical activity. You will also be asked to report your weekly step counts to your research officer on weekly basis via WhatsApp application to the research officer.

### **Study visits:**

Visits will be at the start of the study (Visit 1), a month later (Visit 2) following month (Visit 3) and at 12 months (Visit4). These will be in the wellbeing clinic in your respective health centre where you will be seen by a research officer. Appointments to attend the wellbeing clinic will be different from those of your diabetes clinics. If you wish, you will be reimbursed any travel expenses within reasonable limits. You will be encouraged to come with a family member or a friend to the wellbeing clinic who will be an additional informant for you.

### **Physical Activity Monitor**

Before your first visit you will be invited to wear a physical activity monitor (called an accelerometer) for a week prior to attending your first appointment in the wellbeing clinic. We will also ask you to wear it again prior to your 12 month appointment at the end of the study. This uses temperature and activity sensors against your skin to monitor the amount of activity you do.



**What will happen in the appointed study visits wellbeing clinic?**

Kindly be aware that we need 20 minutes for measurement taking and another 20 minutes for the physical activity consultations. Please try to come with a family member who can provide support through this project. Their contact details will be added to your profile.

**Visit 1:**

Written consent will be taken.

Research measurements will be taken (20 minutes):

1. Measurements of your height, weight, waist circumference and blood pressure.
2. Routine diabetes blood investigations (levels of cholesterol, lipids, glucose, HbA1c) if not done in the week prior to this visit.
3. Questions about your activity levels and views on your health. The sort of questions you will be asked include "In general, how would you describe your health?" You will be given a choice of answers.

Physical activity consultation (20 minutes):

1. Return the physical activity monitor (given earlier) and given a pedometer instead. A pedometer is a small device that counts your daily steps and enables you to read them. It will record and save your step counts for a week. You will be asked to record your daily step counts in a table to be discussed in your next visit.

2. Asked to join a WhatsApp chat to receive monthly physical activity motivational messages and for you to report your weekly step counts that appear in your pedometer. The monthly individual WhatsApp messages from the research officer are mainly to remind you of your appointments and to give you motivational updates on physical activity. The WhatsApp communications will be confidentially shared with your research officer unless you agree to join group discussions where your phone number will be exposed to other project participants. Conversations in group WhatsApp will focus on aims of the study and any issues related to accelerometers, pedometers and other health concerns.

Receive a 20 minutes of physical activity consultation.

Visit 2:

1. Review pedometer logs.
2. Receive a 20 minute physical activity consultation.

Visit 3:

1. Research measurements will be taken.
2. Review pedometer readings and WhatsApp inputs.
3. Receive a 20 minute physical activity consultation.

Visit 4: End of the study

We are also interested in how you found taking part in this study. At the end of your final visit, we will give you a feedback form to complete. If you completed three physical activity consultations, we

may also ask you to take part in an interview about your experiences. This will be face-to-face with a separate member of the research team. We would like to record this discussion for later analysis if you allow us. This recording will be typed up, anonymised, and the tape will then be erased.

### **PART 3: YOUR SAFETY AND RIGHTS**

#### **Do I have to take part?**

No. Taking part in this study is completely voluntary. You can refuse to take part. If you do take part, you can withdraw from the study at any time, and do not have to give us a reason. This will not affect your future medical care. If you do withdraw, all information we have that might identify you will be removed from our files, only your anonymised data will be kept.

#### **What will happen to the information you collect about me?**

All information we collect about you will be kept strictly confidential. At the start of the study you will be assigned an identity ('ID') number to protect your anonymity. This will be used on all questionnaires, blood samples, forms and databases.

Any information we report, such as quotes from interviews, will also be kept anonymous. Your name will not be shown to anyone who is not part of study team. We will inform your GP that you are taking part in case there is any medical reason you are not suitable for the study.

#### **Confidentiality**

Personal (identifiable) information will be kept up to three months after the research is complete.

Only members of the study team will have access to the data we collect from you. However, we are required to allow the data we collect, and any relevant medical notes, to be inspected by monitors.



These monitors would be from the University of Dundee, Ministry of Health. They check that the research is carried out properly, and protect the interests of the people who take part. When the study is complete, the anonymised data or results may be shared in meetings for educational purposes. They will not know who you are.

**Are there any risks to me taking part in this study?**

There are no known risks for you taking part in this study similar to your usual diabetes care.

**Who has reviewed the study?**

Ministry of Health Research and Ethical Review and Approve Committee and the Ethical committee in university of Dundee which has responsibility for scrutinising proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics.

**What if there is a problem?**

If you believe that you have been harmed in any way by taking part in this study, you have the right to complain. You can do this through the quality section in Ministry of Health who responsible of incident management -Telephone number 24782104.

**PART 4: WHAT HAPPENS NOW?**

If you are interested in taking part, the research officer will ask few questions to see if you are illegible and give you an appointment to be seen within a week at the study wellbeing clinic. You will also receive a physical activity monitor to wear and return at your study appointment. You will receive a phone call reminder 2 days prior your appointment.

**Thank you for taking the time to read through this  
information leaflet**



وزارة الصحة  
سلطنة عمان

### "MOVEdiabetes"

دراسة لتعزيز النشاط البدني بين البالغين ممن  
لديهم النوع الثاني من السكري في الرعاية  
الصحية الأولية بسلطنة عمان

معلومات للمشاركين عن الدراسة

### **الجزء الأول: خلفيات هذه الدراسة**

يشكل السكري مشكلة صحية كبيرة في السلطنة، كما نعلم أن العديد من الأفراد لا يمارسون النشاط البدني الكافي، إن ممارسة النشاط البدني المتوسط إلى الشديد لفترة ١٥٠ دقيقة أسبوعيا له فوائد صحية عديدة، وتشمل هذه الفوائد تحسنا بمستويات السكر بالدم وانخفاضا بمعدلات ضغط الدم وازديادا بقوة العضلات وانخفاضا بمستويات الاكتئاب، كما يحس الأفراد الممارسون للنشاط البدني بشعور أفضل وتحسن جودة حياتهم اليومية.

#### **لماذا تمت دعوتي للمشاركة في هذه الدراسة؟**

تجرى هذه الدراسة على الأفراد البالغين الذين لديهم النوع الثاني من السكري والذين تمت متابعتهم في عيادات السكري بالمراكز الصحية لستة أشهر أو أكثر، إننا نرغب في معرفة إن كان بإمكاننا أن نساهم في رفع مستويات النشاط البدني والذي سينعكس إيجابيا على الصحة، والجدير بالذكر ان المراكز الصحية المختلفة لديها مجموعات مختلفة مشاركته في هذه الدراسة.

#### **لماذا ينبغي أن أقرأ هذه المطوية؟**

من المهم قبل أن تقرر إن كنت ستشارك في هذه الدراسة أن تفهم لماذا نجريها وما الذي ستشتمل عليه الدراسة، يرجى قراءة المطوية بعناية وإن كان لديك أية أسئلة فيرجى التواصل مع الدكتورة ثمرة على الرقم 94170961 وستحاول الدكتورة ثمرة الإجابة على أية أسئلة لديكم وتزودكم بالمعلومات التي تحتاجونها، قد ترغب أيضا بمناقشة الأمر مع عائلتك وأصدقائك، ليس عليك أن تتخذ قرارك بالمشاركة فورا.

#### **أين تتم الدراسة؟**

تتم هذه الدراسة في المراكز الصحية بولاية السيب، وتخضع هذه الدراسة لوزارة الصحة بالتعاون مع جامعة السلطان قابوس وجامعة دندي بالمملكة المتحدة.

### **الجزء الثاني: ما الذي سننفي على فعله؟**

في حالة موافقتك على المشاركة بالدراسة سنطلب منك الحضور للمركز الصحي بأربعة زيارات على مدى فترة ١٢ شهرا، وفي خلال هذه الزيارات سيتم أخذ بعض القياسات وبعض فحوصات الدم الروتينية المتعلقة بالسكري وسيتم توجيه بضعة أسئلة لك عن مستويات النشاط البدني لديك وصحتك بشكل عام. سيتم تقديم مشورة لك عن النشاط البدني لفترة ٣٠ دقيقة وسيتم إعطاؤك جهاز قياس عدد خطوات المشي، كما سنطلب منك الاشتراك ببرنامج واتساب الهاتفي والذي سيستخدم من قبل المسئول بالدراسة في المركز الصحي الذي تتابع فيه للتواصل معك بشكل شهري عبر رسائل تحوي معلومات عن النشاط البدني، كما سنطلب منك إخطار مسئول الدراسة بشكل أسبوعي عدد الخطوات التي تمشيها أسبوعيا من خلال برنامج الواتساب.

### **زيارات الدراسة:**

الزيارة الأولى تكون في بداية الدراسة (الزيارة ١)، ثم بعد شهر تكون (الزيارة ٢)، ومن ثم بعد شهر آخر (الزيارة ٣)، وفي الشهر الثاني عشر من الدراسة تكون (الزيارة ٤)، وستكون هذه الزيارات في عيادة الحياة الصحية بالمركز الصحي الذي تتابع فيه حيث سيتم معاينتك من قبل مسئول الدراسة، ستكون مواعيد عيادة الحياة الصحية مختلفة عن مواعيد عيادة السكري ، يفضل الحضور لعيادة الحياة الصحية برفقة عضو من عائلتك أو برفقة صديق والذي سيساعدك على تلقي المعلومات.

### **متابعة النشاط البدني**

قبل زيارتك الأولى ستتم دعوتك لاستعمال جهاز يقيس نشاطك البدني لفترة أسبوع قبل الحضور للموعد، ثم سيطلب منك أن تستعمل نفس الجهاز مرة أخرى قبل موعد الزيارة التي تكون بعد ١٢ شهرا في نهاية الدراسة، وهذا الجهاز يستخدم حرارة الجسم ومجسات النشاط على جلدك لمتابعة مقدار النشاط الذي تمارسه.

### ما الذي سيحدث في زيارات الدراسة بعيادة الحياة الصحية؟

يرجى التكرم علماً بأننا سنحتاج إلى حوالي ٣٠ دقيقة من وقتك لإجراء قياسات ومن ثم ٣٠ دقيقة أخرى لتقديم مشورة عن النشاط البدني، حاول أن تحضر برفقة أحد أفراد العائلة ممن يمكن أن يقدم لك الدعم خلال هذا المشروع، سيتم إضافة أرقام الاتصال بهم في ملفك.

الزيارة ١:

← الحصول على موافقة كتابية منك

← أخذ قياسات الدراسة لك (٣٠ دقيقة)

١- تسجيل قياسات الطول والوزن ومحيط الخصر وضغط الدم

٢- أخذ القياسات التالية إن لم يكن قد تم أخذها في الزيارة السابقة لعيادة السكري بالأسبوع السابق: (مستويات الكوليسترول، الدهون، الجلوكوز، الهيموجلوبين HbA1c)

٣- توجيه بضعة أسئلة عن مستويات النشاط الصحي لديك وعن حالتك الصحية، ستكون الأسئلة كالتالي: (بشكل عام، كيف تصف حالتك الصحية؟ أسئله عن نشاطك البدني أسئله عن الدعم الاجتماعي والقدره على الإستمرار بالنشاط البدني والتغلب على الصعوبات) تكون الإجابة من الاختيارات المعطاة.

← تقديم مشورة عن النشاط البدني (٣٠ دقيقة)

١- إرجاع جهاز قياس النشاط البدني الذي تم إعطاؤه سابقاً واستبداله بجهاز قياس عدد خطوات المشي (بيدوميتر)، البيدوميتر هو جهاز صغير يعد خطوات المشي لديك يوميا ويمكنك من قراءة العدد، كما يقوم بتسجيل وحفظ عدد خطواتك لفترة أسبوع، سيطلب منك أن تسجل عدد خطواتك يوميا في جدول من أجل المشورة في الزيار القادمة.

٢- سيطلب منك الانضمام لحوار في برنامج واتساب لتلقي رسائل شهرية تشجيعية عن النشاط البدني وكذلك لتتمكن من الإبلاغ عن عدد الخطوات

أسبوعيا كما تظهر في جهاز البيدوميتر، هدف رسائل الواتساب الشهرية من المسئول عن الدراسة هو تذكيرك بمواعيدك وإعطائك معلومات حديثة عن النشاط البدني، ستكون مراسلات الواتساب سرية وتصلك فقط من المسئول بالدراسة، وبإمكانك أن تشارك الرسائل التشجيعية مع المشاركين الآخرين بالدراسة إن رغبت بذلك.

#### الزيارة ٢:

- ١- مراجعة سجلات جهاز عداد الخطوات
- ٢- مشورة لفترة ٢٠ دقيقة عن النشاط البدني

#### الزيارة ٣:

- ١- أخذ قياسات الدراسة
- ٢- مراجعة سجلات جهاز عداد الخطوات ورسائل الواتساب
- ٣- مشورة لفترة ٢٠ دقيقة عن النشاط البدني

#### الزيارة ٤: نهاية الدراسة

نرغب بمعرفة انطباعاتك عن المشاركة بالدراسة، بنهاية الزيارة الأخيرة سنعطيك استبياناً لتعبئته، وعند انتهاء جلسات مشورة النشاط البدني الثلاثة فإننا سنطلب منك المشاركة بمقابلة عن تجربتك وستكون هذه المقابلة وجها لوجه مع عضو آخر من فريق الدراسة، سنسجل هذا الحوار للمراجعة لاحقا إن كنت تسمح لنا بذلك، سيتم طباعة نص المقابلة وإزالة بياناتك الشخصية التي تحدد شخصيتك ثم سيتم محو شريط التسجيل.



### **الجزء الثالث: سلامتك وحقوقك**

#### **هل يتوجب علي الاشتراك؟**

لا يتوجب عليك الاشتراك، فالاشتراك في هذه الدراسة تطوعي، ويمكنك الرفض. إذا قمت بالاشتراك، يمكنك الانسحاب في أي وقت، ولا تحتاج لإعطاء سبب للانسحاب. لن يؤثر الانسحاب على العناية الطبية المقدمة لك مستقبلاً، في حال انسحابك من الدراسة، ستُزال كل المعلومات التي تُعين هويتك من بياناتنا. ستبقى البيانات غير المحددة لهويتك عندنا.

#### **ماذا سيحدث للمعلومات التي تجمعونها عني؟**

كل المعلومات التي سنجمعها عنك ستبقى في سرية تامة، سيتم تحديد رقم هوية لك لحماية شخصيتك في بداية الدراسة، وسيستخدم هذا الرقم في الاستبيانات، عينات الدم، نماذج وقواعد البيانات. ستبقى أي معلومات تُؤخذ عنك منك مجهولة الهوية، لن يُعرض اسمك لأي شخص خارج طاقم العمل، سيتم إعلام طبيبك العام بالمركز الصحي باشتراكك في حال وجود سبب صحي لعدم مناسبتك للاشتراك في الدراسة.

#### **الخصوصية**

ستبقى سجلات المعلومات الشخصية (التي تحدد شخصيتك) لفترة ثلاثة أشهر بعد اكتمال الدراسة، ولن يكون بمقدور أي شخص غير أعضاء فريق الدراسة الوصول إلى تلك البيانات التي سنجمعها عنك، ولكن نحن مطالبون بالسماح بمعاينة البيانات التي نجمعها وأية ملحوظات طبية متعلقة من قبل المراقبين، هؤلاء المراقبون سيكونون من جامعة دندي أو وزارة الصحة، وهدف المراقبين هو التأكد من أن الدراسة تتم بشكل صحيح وكذلك حماية مصالح المشاركين بها، وعند اكتمال الدراسة فإن البيانات غير الشخصية أو النتائج سيتم عرضها في المحافل الطبية للأغراض التعليمية ولكنها لن تكشف عن شخصيتك.

### هل هناك أية مخاطر من مشاركتي بالدراسة؟

ليست هناك أية مخاطر معلومة تترتب على مشاركتك بالدراسة والتي تشبه العناية الروتينية للسكري بالعيادة الاعتيادية.

### من الذي راجع مقترح هذه الدراسة؟

تم مراجعة مقترح هذه الدراسة عن طريق لجنة البحوث والمراجعة الأخلاقية والقبول في وزارة الصحة ولجنة الأخلاقيات بجامعة دندي والتي هي مسؤولة عن تمحيص المقترحات للبحوث الطبية على البشر، وبعد المراجعة لم يتم الاعتراض عليها من ناحية الأخلاقيات الطبية.

### ماذا لو حدثت أية مشكلة؟

إن كنت تعتقد أنه قد تسبب لك أي أذى من المشاركة بالدراسة فإن لديك الحق بالشكوى، وبإمكانك أن تقدم الشكوى من خلال قسم الجودة في وزارة الصحة والذين هم مسئولون عن التعامل مع مثل هذه الأمور عن طريق الرقم 24782104.



### الجزء ٤: ماذا سحدث الآن؟

إن كنت راغبا بالمشاركة فإن المسئول بالدراسة سيسألك بضعة أسئلة ليقرر إن كانت تنطبق عليك مواصفات القبول بالدراسة ثم سيعطيك موعدا خلال أسبوع في عيادة الحياة الصحية، كما سيتم إعطاؤك جهاز مراقبة للنشاط البدني لتلبسه وترجعه في وقت الموعد، سيتم الاتصال بك قبل يومين من الموعد لتذكيرك به.

### شكرا لوقتكم وقراءتكم هذه المطوية



**Appendix 6.5: The “MOVEdiabetes” participants’ information sheets in both English and Arabic languages for the comparison group**



**“MOVEdiabetes”**

A Trial to Promote Physical Activity for Adults with Type 2 Diabetes in Primary Health Care in Oman

**INFORMATION ABOUT THIS STUDY FOR PARTICIPANTS**

“MOVEdiabetes” Participant Information Sheet (Comparison),  
V4.0, 27<sup>th</sup> November 2015

## **PART 1: BACKGROUND TO THE STUDY**

Diabetes is a major health problem in Oman. We also know that many people are very sedentary. Increasing to 150 minutes per week of moderate or vigorous activity can have many health benefits. These include improvements in blood tests, lower blood pressure, increased muscle strength and lower levels of depression. People who exercise report feeling better and an improved quality of life.

### **Why am I being invited to take part in this study?**

This study is being carried out with adults who have Type 2 diabetes, and who have been followed up in a health centre diabetes clinic for 6 months or more. We want to see whether we can help increase physical activity levels which will reflect positively on health by introducing physical activity intervention. Different health centres have different groups within the study.

### **Why should I read this leaflet?**

Before you decide whether or not you would like to take part in the study, it is important that you understand why we are doing it, and what it involves. Please read this leaflet carefully. If you have any questions, you should contact Dr.Thamra on 94170961. Dr.Thamra will try to answer any questions that you have and give you any further information you may need. You may also want to discuss it with your family and friends. You do not have to make an immediate decision about taking part in the study.

### **Where is the study being carried out?**

This study is being carried out in health centers in Seeb. The study is being led by Ministry of Health, together with Sultan Qaboos University and University of Dundee (UK).

## PART 2: WHAT WILL I HAVE TO DO?

If you agree to take part we will ask you to attend 3 visits over a 12 month period. The visits will be to take some measurements, routine diabetes blood tests and to ask you some questions about exercise levels and overall health.

### Study Visits

Visits will be at the start of the study (baseline-Visit 1), and 3 months later (Visit 2) and the last visit at 12 months (Visit 3). These will be done in the wellbeing clinic in your respected health centre where you will be seen by a research officer. Appointments to attend the wellbeing clinics will be different from those of your diabetes clinics. If you wish, you will be reimbursed any travel expenses within reasonable limits.

- **Physical Activity Monitor**

Before your first visit you will be invited to wear a physical activity monitor (called an accelerometer) for a week prior to attending your appointment. We will also ask you to wear it again prior to your 12 month appointment at the end of the study. This uses temperature and activity sensors against your skin to monitor the amount of activity you do.

### Study Visits- what will happen?

Kindly be aware that we need 20 minutes for measurement taking.

- A written consent will be taken in visit 1 prior to taking the study baseline measurements.
- Return the physical activity monitor (visit 1 & 3)
- Take measurements of your height, weight, waist circumference and blood pressure.

- Take routine diabetes blood investigations (levels of cholesterol, lipids, glucose, and HbA1c if not recorded in your visit to diabetes clinic the week before.
- Ask you questions about your activity levels and views on your health. The sort of questions you will be asked include "In general, how would you describe your health?" You will be given a choice of answers.

**End of the study – Final visit (after 12 months)**

The last study measurements will be taken and participants will be offered a physical activity consultation and a pedometer for personal use.

### **PART 3: YOUR SAFETY AND RIGHTS**

#### **Do I have to take part?**

No. Taking part in this study is completely voluntary. You can refuse to take part. If you do take part, you can withdraw from the study at any time, and do not have to give us a reason. This will not affect your future medical care. If you do withdraw, all information we have that might identify you will be removed from our files, only your anonymised data will be kept.

#### **What will happen to the information you collect about me?**

All information we collect about you will be kept strictly confidential. At the start of the study you will be assigned an identity ('ID') number to protect your anonymity. This will be used on all questionnaires, blood samples, forms and databases.

Any information we report will also be kept anonymous. Your name will not be shown to anyone who is not part of study team. We will inform your GP that you are taking part in case there is any medical reason you are not suitable for the study.

#### **Confidentiality**

Personal (identifiable) information will be kept up to three months after the research is complete.

Only members of the study team will have access to the data we collect from you. However, we are required to allow the data we collect, and any relevant medical notes, to be inspected by monitors. These monitors would be from the University of Dundee or Ministry of Health. They check that the research is carried out properly, and protect the interests of the people who take part. When the study is complete, the anonymised data or results may be shared in meetings for educational purposes. They will not know who you are.



**Are there any risks to me taking part in this study?**

There are no known risks for you taking part in this study similar to your usual diabetes care.

**Who has reviewed the study?**

The Ministry of Health Research and Ethical Review and Approval Committee and the Ethical committee in University of Dundee which has responsibility for scrutinising proposals for medical research on humans, have examined the proposal and have raised no objections from the point of view of medical ethics.

**What if there is a problem?**

If you believe that you have been harmed in any way by taking part in this study, you have the right to complain. You can do this through the quality section in the Ministry of Health who are responsible for incident management -Telephone number 24782104.

**PART 4: WHAT HAPPENS NOW?**

If you are interested in taking part, the research officer will ask few questions to see if you are illegible and give you an appointment to be seen within a week at the study wellbeing clinic. You will also receive a physical activity monitor to wear and return at your study appointment. You will receive a phone call reminder 2 days prior your appointment.

**Thank you for taking the time to read through this  
information leaflet**



Ministry of Health  
Sultanate of Oman

وزارة الصحة  
سلطنة عمان

### "MOVEdiabetes"

دراسة لتعزيز النشاط البدني بين البالغين ممن  
لديهم النوع الثاني من السكري في الرعاية  
الصحية الأولية بسلطنة عمان

معلومات للمشاركين عن الدراسة

### **الجزء الأول: خلفيات هذه الدراسة**

يشكل السكري مشكلة صحية كبيرة في السلطنة، كما نعلم أن العديد من الأفراد لا يمارسون النشاط البدني الكافي، إن ممارسة النشاط البدني المتوسط إلى الشديد لفترة ١٥٠ دقيقة أسبوعيا له فوائد صحية عديدة، وتشمل هذه الفوائد تحسنا بمستويات السكر بالدم وانخفاضا بمعدلات ضغط الدم وازديادا بقوة العضلات وانخفاضا بمستويات الاكتئاب، كما يحس الأفراد الممارسون للنشاط البدني بشعور أفضل وتحسن جودة حياتهم.

#### **لماذا تمت دعوتي للمشاركة في هذه الدراسة؟**

تجرى هذه الدراسة على الأفراد البالغين الذين لديهم النوع الثاني من السكري والذين تمت متابعتهم في عيادات السكري بالمراكز الصحية لستة أشهر أو أكثر، إننا نرغب في معرفة إن كان بإمكاننا أن نساهم في رفع مستويات النشاط البدني والذي سينعكس إيجابيا على الصحة، والجدير بالذكر ان المراكز الصحية المختلفة لديها مجموعات مختلفة في الدراسة.

#### **لماذا ينبغي أن أقرأ هذه المطوية؟**

من المهم قبل أن تقرر إن كنت ستشارك في هذه الدراسة أن تفهم لماذا نجرىها وما الذي ستشتمل عليه الدراسة، يرجى قراءة المطوية بعناية وإن كان لديك أية أسئلة فيرجى التواصل مع الدكتورة ثمرة على الرقم 94170961 وستحاول الدكتورة ثمرة الإجابة على أية أسئلة لديكم وتزودكم بالمعلومات التي تحتاجونها، قد ترغب أيضا بمناقشة الأمر مع عائلتك وأصدقائك، ليس عليك أن تتخذ قرارك بالمشاركة فورا.

#### **أين تتم الدراسة؟**

تتم هذه الدراسة في المراكز الصحية بولاية السيب، وتخضع هذه الدراسة لوزارة الصحة بالتعاون مع جامعة السلطان قابوس وجامعة دندي بالمملكة المتحدة.



### **الجزء الثاني: ما الذي سنبغي علي فعله؟**

في حالة موافقتك على المشاركة بالدراسة سنطلب منك الحضور للمركز الصحي لثلاث زيارات على مدى فترة ١٢ شهرا، وفي خلال هذه الزيارات سيتم أخذ بعض القياسات وبعض فحوصات الدم الروتينية المتعلقة بالسكري وسيتم توجيه بضعة أسئلة لك عن مستويات النشاط البدني لديك وصحتك بشكل عام.

#### **الزيارات الخاصة بالدراسة**

ستكون الزيارات كالتالي: زيارة عن بدء الدراسة (تسمى الزيارة الأساسية-١)، ثم زيارة بعد ثلاثة أشهر (الزيارة-٢) ثم زيارة عند ١٢ شهرا بعد البدء (الزيارة-٣)، وستتم هذه الزيارات في عيادة الحياة الصحية في المركز الصحي الذي تتابع فيه حيث سيتم معاينتك من قبل مسئول بالدراسة، المواعيد التي سيتم إعطاؤك إياها لعيادة الحياة الصحية ستكون مختلفة عن تلك التي لعيادة السكري، وإن رغبت فيمكننا أن نقدم لك تعويضات في حدود مقبولة لما تتكلفه من مصاريف نقل إضافية من إلى المركز الصحي لتلك الزيارات.

#### **• متابعة النشاط البدني**

قبل زيارتك الأولى ستتم دعوتك لاستعمال جهاز يقيس نشاطك البدني لفترة أسبوع قبل الحضور للموعد، ثم سيطلب منك أن تستعمل نفس الجهاز مرة أخرى قبل موعد الزيارة-٣ في نهاية الدراسة، وهذا الجهاز يستخدم حرارة الجسم ومجسات النشاط على جلدك لمتابعة مقدار النشاط الذي تمارسه.

#### **زيارات الدراسة- ما الذي سيحدث فيها؟**

يرجى التكرم علما بأننا سنحتاج إلى حوالي ٢٠ دقيقة من وقتك لإجراء ما يلي:

- الحصول على موافقة كتابية منك في الزيارة الأولى قبل أخذ قياسات الدراسة الأساسية منك.
- إرجاع جهاز قياس النشاط البدني (الزيارة ١ والزيارة ٣)

- تسجيل قياسات الطول والوزن ومحيط الخصر وضغط الدم
- أخذ القياسات التالية إن لم يكن قد تم أخذها في الزيارة السابقة لعيادة السكري بالأسبوع السابق: (مستويات الكوليسترول، الدهون، الجلوكوز، الهيموجلوبين HbA1c).
- توجيه بضعة أسئلة عن مستويات النشاط الصحي لديك وعن حالتك الصحية، ستكون الأسئلة كالتالي: (بشكل عام، كيف تصف حالتك الصحية؟ أسئله عن نشاطك البدني اسئله عن الدعم الاجتماعي والقدرة على الإستمرار بالنشاط البدني والتغلب على الصعوبات) تكون الإجابة من الاختيارات المعطاة.

#### **انتهاء الدارسة - الزيارة الأخيرة (بعد ١٢ شهرا)**

سيتم أخذ قياسات الزيارة الأخيرة، وسيتم تقديم مشورة للمشاركين عن النشاط البدني مع عداد لخطوات المشي للاستعمال الشخصي.

#### **الجزء الثالث: سلامتك وحقوقك**

##### **هل يتوجب علي الاشتراك؟**

لا يتوجب عليك الاشتراك، فالاشتراك في هذه الدراسة تطوعي، ويمكنك الرفض. إذا قمت بالاشتراك، يمكنك الانسحاب في أي وقت، ولا تحتاج لإعطاء سبب للانسحاب. لن يؤثر الانسحاب على العناية الطبية المقدمة لك مستقبلا، في حال انسحابك من الدراسة، سنُزال كل المعلومات التي تُعين هويتك من بياناتنا. ستبقى البيانات غير المحددة لهويتك عندنا.

##### **ماذا سيحدث للمعلومات التي تجمعونها عني؟**

كل المعلومات التي سنجمعها عنك ستبقى في سرية تامة، سيتم تحديد رقم هوية لك لحماية شخصيتك في بداية الدراسة، وسيستخدم هذا الرقم في الاستبيانات، عينات الدم، نماذج وقواعد البيانات.

ستبقى أي معلومات تُؤخذ عنك منك مجهولة الهوية، لن يُعرض اسمك لأي شخص خارج طاقم العمل، سيتم إعلام طبيبك العام بالمركز الصحي باشتراكك في حال وجود سبب صحي لعدم مناسبتك للاشتراك في الدراسة.

### الخصوصية

ستبقى سجلات المعلومات الشخصية (التي تحدد شخصيتك) لفترة ثلاثة أشهر بعد اكتمال الدراسة، ولن يكون بمقدور أي شخص غير أعضاء فريق الدراسة الوصول إلى تلك البيانات التي سنجمعها عنك، ولكن نحن مطالبون بالسماح بمعاينة البيانات التي نجمعها وأية ملحوظات طبية متعلقة من قبل المراقبين، هؤلاء المراقبون سيكونون من جامعة دندي أو وزارة الصحة، وهدف المراقبين هو التأكد من أن الدراسة تتم بشكل صحيح وكذلك حماية مصالح المشاركين بها، وعند اكتمال الدراسة فإن البيانات غير الشخصية أو النتائج سيتم عرضها في المحافل الطبية للأغراض التعليمية ولكنها لن تكشف عن شخصيتك.

### هل هناك أية مخاطر من مشاركتي بالدراسة؟

ليست هناك أية مخاطر معلومة تترتب على مشاركتك بالدراسة والتي تشبه العناية الروتينية للسكري بالعيادة الاعتيادية.

### من الذي راجع مقترح هذه الدراسة؟

تم مراجعة مقترح هذه الدراسة عن طريق لجنة البحوث والمراجعة الأخلاقية والقبول في وزارة الصحة ولجنة الأخلاقيات بجامعة دندي والتي هي مسؤولة عن تمحيص المقترحات للبحوث الطبية على البشر، وبعد المراجعة لم يتم الاعتراض عليها من ناحية الأخلاقيات الطبية.

### ماذا لو حدثت أية مشكلة؟

إن كنت تعتقد أنه قد تسبب لك أي أذى من المشاركة بالدراسة فإن لديك الحق بالشكوى، وبإمكانك أن تقدم الشكوى من خلال قسم الجودة في وزارة الصحة والذين هم مسئولون عن التعامل مع مثل هذه الأمور عن طريق الرقم 24782104.

**الجزء ٤: ماذا سيحدث الآن؟**

إن كنت راغبا بالمشاركة فإن المسئول بالدراسة سيسألك بضعة أسئلة ليقرر إن كانت تنطبق عليك مواصفات القبول بالدراسة ثم سيعطيك موعدا خلال أسبوع في عيادة الحياة الصحية، كما سيتم إعطاؤك جهاز مراقبة للنشاط البدني لتلبسه وترجعه في وقت الموعد، سيتم الاتصال بك قبل يومين من الموعد لتذكيرك به.

**شكرا لوقتكم وقراءتكم هذه المطوية**

## Appendix 6.6: The “MOVEdiabetes” participants’ consent forms (intervention group)



### CONSENT FORM

#### “MOVEdiabetes” A Trial to Promote Physical Activity for Adults with Type 2 Diabetes in Primary Health Care in Oman

Name of Researcher: .....

**Please initial box**

- |  |                          |
|--|--------------------------|
| 1. I confirm that I have read and understood the information leaflet dated ----- /2016 for the above study. I have had the opportunity to consider the information, ask questions and have these answered to my satisfaction.  | <input type="checkbox"/> |
| 2. I understand that my participation is voluntary, that I am free to withdraw at any time without giving a reason, and without my medical care or legal rights being affected. I understand that if I withdraw any unidentifiable (anonymised) data collected until my withdrawal will be retained. | <input type="checkbox"/> |
| 3. I understand that relevant sections of the data collected during the study may be looked at by individuals from the University of Dundee and from Ministry of Health. I give permission for these individuals to have access to my anonymised data.   | <input type="checkbox"/> |
| 4. I understand that it is a requirement from the Research and Ethical Review and Approval Committee that the data collected is available for sharing with others at the end of the study. I give permission for these individuals to have access to my anonymised data.                             | <input type="checkbox"/> |
| 5. I understand if I am interviewed at the end of the study, the interview will be digitally recorded, typed up, anonymised and then the recording will be erased.   | <input type="checkbox"/> |
| 6. I understand that if I am interviewed at the end of the study, the comments I make may be quoted in any reports, papers or presentations that are produced as a result of the research, but that they will be kept anonymous.   | <input type="checkbox"/> |
| 7. I agree to diabetes laboratory investigations being taken at the start of the study, at 3 months and 12 months.   | <input type="checkbox"/> |
| 8. I agree to my GP being informed that I am taking part in the study and of any abnormal results.   | <input type="checkbox"/> |
| 9. I agree to participate in WhatsApp telephone communications.  | <input type="checkbox"/> |
| 10. I agree to take part in the above study.   | <input type="checkbox"/> |
| 11. I agree to being approached for future research studies.   | <input type="checkbox"/> |

Name of participant	Date	Signature
---------------------	------	-----------

Name of person taking consent	Date	Signature
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When complete, 1 should be kept by the participant; and 1 (original) should be kept in the researcher site file.



### استمارة الموافقة

MOVEDiabetes هي دراسة لتعزيز النشاط البدني لدى البالغين ممن لديهم النوع الثاني من السكري في الرعاية الصحية الأولية بسلطنة عمان

#### يرجى إشارة في المربع-أؤكد على:

- ١- أنني قرأت وفهمت ورقة المعلومات للدراسة المذكورة أعلاه، وكانت لدي الفرصة الكافية لاستيعاب تلك المعلومات وتوجيه الأسئلة والحصول على الإجابات بشكل مرض.
- ٢- أنني أدرك أن مشاركتي بالدراسة تطوعية وأنني لدي الحرية بالانسحاب منها في أي وقت من دون الحاجة إلى إبداء الأسباب لذلك، وأن الانسحاب لن يؤثر بأي شكل على العناية الطبية أو الحقوق القانونية التي أتمتع بها، أنني أدرك أنه في حالة انسحابي فإن البيانات غير المعروفة (التي لا تحوي ما يدل على شخصيتي) والتي تم أخذها مني إلى لحظة انسحابي سيتم الاحتفاظ بها في الدراسة.
- ٣- أنني أدرك أنه قد يتم معاناة أقسام معينة من البيانات التي تم جمعها مني أثناء الدراسة من قبل أفراد من جامعة دندي أو من وزارة الصحة وأنني أسمح لهؤلاء الأفراد بمعالجة بياناتي التي لا تدل على شخصيتي.
- ٤- أنني أدرك أن من متطلبات لجنة البحوث والمراجعة الأخلاقية والقبول أن تكون البيانات التي تم جمعها في الدراسة متوفرة للمشاركة مع الآخرين بعد انتهاء الدراسة، وأنني أسمح للأفراد الآخرين بالاطلاع على بياناتي التي لا تدل على شخصيتي.
- ٥- أنني أدرك أنه إن تم إجراء مقابلة معي في نهاية الدراسة فإن تلك المقابلة ستكون مسجلة إلكترونياً وسيتم طباعة نصها ثم إزالة ما يدل على شخصيتي منها ثم سيتم محو التسجيل.
- ٦- أنني أدرك أنه إن تم إجراء مقابلة معي في نهاية الدراسة فإن التعليقات التي ألقاها قد يتم اقتباسها في أي تقرير أو مقالة أو عرض يتم إنتاجه للبحوث ولكن لن يكون هناك ما يدل على شخصيتي.
- ٧- أنني أوافق على أن يتم أخذ فحوصات مختبرية للسكري مني في بداية الدراسة وبعد ٣ أشهر وبعد ١٢ شهراً.
- ٨- أنني أوافق على أن يتم إعلام الطبيب بالمركز الصحي عن مشاركتي بالدراسة وعن أية نتائج غير طبيعية يتم الحصول عليها.
- ٩- أنني أوافق على أن أشارك بالتواصل من خلال برنامج واتساب بالهاتف النقال.
- ١٠- أنني أوافق على المشاركة بالدراسة المذكورة في أعلاه.
- ١١- أنني أوافق على أن يتم الاتصال بي للدراسات والبحوث في المستقبل.

اسم المشارك بالدراسة	التاريخ	التوقيع
اسم المسئول عن استمارة الموافقة	التاريخ	التوقيع



## Appendix 6.7: The “MOVEdiabetes” participants’ consent forms (comparison group)



### CONSENT FORM

#### “MOVEdiabetes” A Trial to Promote Physical Activity for Adults with Type 2 Diabetes in Primary Health Care in Oman

Name of Researcher: .....

Please initial box

1. I confirm that I have read and understood the information leaflet dated -----  
/2016 for the above study. I have had the opportunity to consider the  
information, ask questions and have these answered to my satisfaction. ☐
2. I understand that my participation is voluntary, that I am free to withdraw at any  
time without giving a reason, and without my medical care or legal rights being  
affected. I understand that if I withdraw any unidentifiable (anonymised) data  
collected until my withdrawal will be retained. ☐
3. I understand that relevant sections of the data collected during the study may be  
looked at by individuals from the University of Dundee and from Ministry of  
Health. I give permission for these individuals to have access to my anonymised  
data. ☐
4. I understand that it is a requirement from the Research and Ethical Review and  
Approval Committee that the data collected is available for sharing with others at  
the end of the study. I give permission for these individuals to have access to  
my anonymised data. ☐
5. I understand if I am interviewed at the end of the study, the interview will be  
digitally recorded, typed up, anonymised and then the recording will be erased. ☐
6. I understand that if I am interviewed at the end of the study, the comments I  
make may be quoted in any reports, papers or presentations that are produced  
as a result of the research, but that they will be kept anonymous. ☐
7. I agree to diabetes laboratory investigations being taken at the start of the  
study, at 3 months and 12 months. ☐
8. I agree to my GP being informed that I am taking part in the study and of any  
abnormal results. ☐

\_\_\_\_\_  
Name of participant                      Date                      Signature

\_\_\_\_\_  
Name of person taking consent      Date                      Signature

When complete, 1 should be kept by the participant; and 1 (original) should be kept in the  
researcher site file.



### استمارة الموافقة

MOVEDiabetes هي دراسة لتعزيز النشاط البدني لدى البالغين ممن لديهم النوع الثاني من السكري في الرعاية الصحية الأولية بسلطنة عمان

#### يرجى إشارة في المربع-أؤكد على:

- ١- أنني قرأت وفهمت ورقة المعلومات للدراسة المذكورة أعلاه، وكانت لدي الفرصة الكافية لاستيعاب تلك المعلومات وتوجيه الأسئلة والحصول على الإجابات بشكل مرض.
- ٢- أنني أدرك أن مشاركتي بالدراسة تطوعية وأنني لدي الحرية بالانسحاب منها في أي وقت من دون الحاجة إلى إبداء الأسباب لذلك، وأن الانسحاب لن يؤثر بأي شكل على العناية الطبية أو الحقوق القانونية التي أتمتع بها، أنني أدرك أنه في حالة انسحابي فإن البيانات غير المعروفة (التي لا تحوي ما يدل على شخصيتي) والتي تم أخذها مني إلى لحظة انسحابي سيتم الاحتفاظ بها في الدراسة.
- ٣- أنني أدرك أنه قد يتم معاناة أقسام معينة من البيانات التي تم جمعها مني أثناء الدراسة من قبل أفراد من جامعة دندي أو من وزارة الصحة وأنني أسمح لهؤلاء الأفراد بمعاناة بياناتي التي لا تدل على شخصيتي.
- ٤- أنني أدرك أن من متطلبات لجنة البحوث والمراجعة الأخلاقية والقبول أن تكون البيانات التي تم جمعها في الدراسة متوفرة للمشاركة مع الآخرين بعد انتهاء الدراسة، وأنني أسمح للأفراد الآخرين بالاطلاع على بياناتي التي لا تدل على شخصيتي.
- ٥- أنني أدرك أنه إن تم إجراء مقابلة معي في نهاية الدراسة فإن تلك المقابلة ستكون مسجلة إلكترونياً وسيتم طباعة نصها ثم إزالة ما يدل على شخصيتي منها ثم سيتم محو التسجيل.
- ٦- أنني أدرك أنه إن تم إجراء مقابلة معي في نهاية الدراسة فإن التعليقات التي ألقاها قد يتم اقتباسها في أي تقرير أو مقالة أو عرض يتم إنتاجه للبحوث ولكن لن يكون هناك ما يدل على شخصيتي.
- ٧- أنني أوافق على أن يتم أخذ فحوصات مختبرية للسكري مني في بداية الدراسة وبعد ٣ أشهر وبعد ١٢ شهراً.
- ٨- أنني أوافق على أن يتم إعلام الطبيب بالمركز الصحي عن مشاركتي بالدراسة وعن أية نتائج غير طبيعية يتم الحصول عليها.

التوقيع	التاريخ	اسم المشارك بالدراسة
التوقيع	التاريخ	اسم المسئول عن استمارة الموافقة



**Appendix 6.8: “MOVEdiabetes” participants’ follow-up booklet****“Movediabetes”**

A Trial to Promote Physical Activity for Adults with  
Type 2 Diabetes in Primary Health Care in Oman

**Participant Follow up Booklet  
(Intervention group)**



FIRST CONTACT:

ACCELEROMETERS GIVEN (IF IN ACCELEROMETER GROUP)

SCHEDULE OF VISITS

	May-2016 Visit-1(Baseline) dates				July-2016 Visit-3(3months follow-up) dates				March-2017 12months follow- up dates			
week	1	2	3	4	9	10	11	12	48	49	50	51
1												
2												
3												
4												

Check list:

☐ Accelerometer returning date given

**VISIT 2: Pedometer findings-step counts**

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1							
Week 2							
Week 3							
Week 4							

**VISIT 3: Pedometer findings-step counts**

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1							
Week 2							
Week 3							
Week 4							

## Check list:

- ☐ Accelerometer returning date given  
☐ Questionnaires completed  
☐ Investigations completed

3 of 4

Telephone number: 97034089

Email:


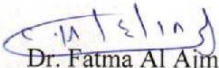

movediabetes2@gmail.com

## Check list:

- ☐ Accelerometer returning date given  
☐ Questionnaires completed  
☐ Investigations completed

4 of 4

## Appendix 6.9: Ethical approval for the Directorate of Health Services. Muscat

<p><b>Sultanate of Oman</b> MINISTRY OF HEALTH Directorate General of Health Services GOVERNORATE OF MUSCAT <i>Director General Office</i></p>		<p><b>سلطنة عُمان</b> <b>وزارة الصحة</b> المديرية العامة للخدمات الصحية لحافضة مسقط مكتب المدير العام</p>
<p>Ref: MH/DGHS/DG/ 78</p> <p>To Dr. Thamra Al- Ghafri</p>		
<p>Re/ Research &amp; Ethics Committee Feedback</p>		
<p>After Compliments,</p> <p>We are pleased to inform you that your research “MOVE diabetes” a trial to promote physical activity for adults with Type 2 diabetes in primary health care in Oman, which is approved by the central research and ethical review and approve committee dated 5.1.2016 is reciprocally approved by the regional research committee. Therefore, the use of whatsapp (a telephone application) within the intervention to send educational message indicated in the submitted proposal is approved.</p> <p>With kind regards,</p> <div style="display: flex; align-items: center; justify-content: center;"> <div style="text-align: center; margin-right: 20px;">   <b>Dr. Fatma Al Ajmi</b>              Director General              Chairperson of Regional Research Committee- Muscat           </div> <div style="text-align: center;">  </div> </div>		
<div style="display: flex; justify-content: space-between;"> <div> <p>P.O. Box : 358, Mina Al-Fahal Postal Code : 116, Sultanate of Oman Fax : 24782104 - Fax : 24782102</p> </div> <div style="text-align: right;"> <p>ص.ب: ٣٥٨ ميناء الفحل الرمز البريدي: ١١٦، سلطنة عُمان فاكس: ٢٤٧٨٢١٠٤ - فاكس: ٢٤٧٨٢١٠٢</p> </div> </div>		

## Appendix 7.1: The published results (primary and secondary outcomes) of the “MOVEdiabetes” study

Open access

Original research

**BMJ Open  
Diabetes  
Research  
& Care**

# ‘MOVEdiabetes’: a cluster randomized controlled trial to increase physical activity in adults with type 2 diabetes in primary health in Oman

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### ABSTRACT

**Objective** This study examined the impact of a multicomponent intervention to increase physical activity (PA) in adults with type 2 diabetes (T2D) in Oman.

**Research design and methods** This is a cluster randomized controlled trial in eight primary health centers. Participants were physically inactive, aged  $\geq 18$  years, and with no contraindication to PA. Patients attending intervention health centers (n=4) received the ‘MOVEdiabetes’ intervention, which consisted of personalized, individual face-to-face consultations by dietitians. Pedometers and monthly telephone WhatsApp messages were also used. Patients attending comparison health centers received usual care. The primary outcome was change in PA [Metabolic Equivalent(MET).min/week] after 12 months assessed by the Global Physical Activity Questionnaire. The secondary outcomes were changes in daily step counts, sitting time, weight, body mass index, glycated hemoglobin, blood pressure and lipids.

**Results** Of the 232 participants (59.1% female, mean (SD) age 44.2 (8.1) years), 75% completed the study. At 12 months, the mean change in MET.min/week was +631.3 (95% CI 369.4 to 893.2) in the intervention group (IG) vs +183.2 (95% CI 83.3 to 283.0) in the comparison group, with a significant between-group difference of +447.4 (95% CI 150.7 to 744.1). The odds of meeting PA recommendations were 1.9 times higher in the IG (95% CI 1.2 to 3.3). Significant between-group differences in favor of IG were detected for mean steps/day (+757, 95% CI 18 to 1531) and sitting time hours/ per day (−1.5, 95% CI −2.4 to −0.7). Clinical measures of systolic and diastolic blood pressure and triglycerides also showed significant intervention effects.

**Conclusions** ‘MOVEdiabetes’ was effective in increasing PA, the likelihood of meeting PA recommendations, and providing cardioprotective benefits in adults with T2D attending primary care.

### INTRODUCTION

Similar to global trends, diabetes prevalence in Oman is increasing. Recent estimates in Omani adults are in the order of 12.6%, which is exceeding global rates.<sup>1</sup> This increase is predominantly in type 2 diabetes (T2D),

### Significance of this study

#### What is already known about this subject?

- ▶ The relationship between physical activity (PA) and type 2 diabetes (T2D) has been widely researched.
- ▶ Minimal progress has been made in the implementation of research findings within everyday diabetes care practice.

#### What are the new findings?

- ▶ The current 1-year intervention was delivered in a real setting and using existing healthcare staff.
- ▶ This paper shows that the ‘MOVEdiabetes’ intervention was effective in increasing the PA levels in inactive adults with T2D.
- ▶ Secondary outcomes showed positive changes in blood pressure and triglycerides.

#### How might these results change the focus of research or clinical practice?

- ▶ Personalized PA consultations can be delivered within routine diabetes primary care.
- ▶ The role of the existing staff in diabetes primary care, namely dietitians, could be extended to deliver PA promotional methods, including PA consultations, use of pedometers and ‘WhatsApp’ monthly messages.

which is preventable through lifestyle modifications.<sup>2</sup> While diet and body weight are already part of routine diabetes management, physical activity (PA) advice and guidance is not routinely provided.

Evidence on the positive effects of PA on the management of T2D is strong, yet evidence on the effective ways for PA implementation as part of diabetes care is lagging behind.<sup>3,4</sup> Lifestyle modification including PA can result in improved glycemic control, lower blood sugar levels, reduced body fat, and a reduced risk of serious complications and premature mortality.<sup>5–7</sup> To achieve clinical benefits, the





WHO recommends at least 150 min of moderate-intensity PA or 75 min of vigorous-intensity PA per week, or a combination of the two.<sup>8</sup> However, the majority of people with T2D are physically inactive compared with national norms in both Western (over 60% in USA)<sup>9</sup> and Arabic-speaking countries (over 80% in Oman and Lebanon).<sup>10,11</sup>

Current evidence on PA interventions in diabetes primary care comes mostly from Western countries, with mixed results.<sup>4</sup> PA interventions have differed in their setting (clinical vs community), intervention methods (PA consultations, exercise sessions, or use of technology) and duration (short of 3–6 months vs long ≥12 months).<sup>4</sup> Incorporating behavior change techniques (BCTs) in PA interventions has been shown to help individuals move from ‘inactive’ to ‘active’ stages of change for PA.<sup>12</sup> While there are a large number of BCTs, these have been standardized by Abraham and Michie<sup>13</sup> to assist the development of lifestyle interventions, and more recent updates describe an extensive range of opportunities to assist the design of context-specific programs.<sup>13–15</sup> However, further research is needed to establish how far the BCTs can lead to more efficient designs for improving the PA behaviors in the context of diabetes care.<sup>14</sup> Avery *et al*<sup>12</sup> (2012–2015) distinguished five context-appropriate BCTs for use during time-constrained consultations in diabetes care. These include ‘prompt focus on past success’, ‘barrier identification’, ‘use of follow-up prompts’, ‘providing information on where and when to perform the behaviour’ and ‘prompt review of behavioural goals of PA’.<sup>12</sup> Further research is needed to investigate the BCTs that could be effective in promoting PA in Arabic-speaking countries.

Evidence on the effectiveness of personalized PA consultations in clinical settings along with other supportive methods (eg, use of pedometers and telephones)<sup>15–17</sup> has been reported in many studies in the West, including guidelines on how to deliver them.<sup>18–21</sup> To address the sociodemographic, cultural and clinical diversities, the impact of such approaches on PA promotion in local routine diabetes primary care setting in the Middle East is yet to be explored.

Consistent with the socioecological model of health behavior<sup>22</sup> and the Behaviour Change Wheel model,<sup>14</sup> the work presented in this paper is underpinned by a series of formative studies undertaken in adults with T2D and diabetes primary care providers in Oman.<sup>23–25</sup> The results showed that face-to-face PA consultations linked to BCTs, devices to support walking such as pedometers, and use of a telephone application (WhatsApp) could be promising components in an intervention design. Hence, these methods have been used in the ‘MOVEdiabetes’ intervention,<sup>26</sup> the trial protocol for which is published elsewhere.<sup>26</sup>

The aim of this paper is to describe the effectiveness of the multicomponent ‘MOVEdiabetes’ intervention on change in PA levels (primary outcome), and changes in objectively measured steps/day, sitting time (hours/ per

day), weight, body mass index (BMI), glycated hemoglobin (HbA1c), blood pressure and lipids (secondary outcomes).

## METHODS

### Study design and randomization

The study was a 1-year (April 2016–June 2017) cluster randomized controlled trial of the ‘MOVEdiabetes’ intervention versus usual care.<sup>26</sup> Out of the 26 health centers in Muscat, 8 were randomly selected by an independent statistician using random numbers table generated in SPSS V.22. Health centers were then randomized to deliver either the intervention in the intervention group (IG) health centers (n=4) or usual care in the comparison group (CG) health centers (n=4).<sup>26</sup>

### Study population and recruitment

Eligible participants were adults aged ≥18 years with T2D who had been attending health centers for at least 6 months for diabetes care and were screened by recruited project officers (POs) as being inactive using the Scottish Physical Activity Screening Questionnaire,<sup>27</sup> with no contraindication to increasing PA, and able to provide written informed consent.<sup>26</sup>

### Sample size

To demonstrate a 50% between-group difference in PA levels (MET.min/week) over 12 months, to be detected at a power of 80%, and a significance level of 5%, 128 participants were required to complete the study (64 in each arm).<sup>26</sup> This sample size (n) was calculated based on an estimation from formative work of the SD of mean PA levels of 145 MET.min/week<sup>25</sup> and mean sitting time (hours/day) of 0.2 with intraclass correlation coefficient of 0.1.<sup>28</sup> Based on a dropout rate of 20%, 154 patients were required to participate (77 in each arm). Assuming a recruitment rate of 70%, it was estimated that 220 potential eligible patients were required to be approached.<sup>26</sup>

### Ethics

Ethical approval was obtained from the Omani Research and Ethical Review and Approve Committee in the Ministry of Health and reciprocally approved in the University of Dundee (online supplementary material 1). In addition to providing informed consent, individuals were given the right to withdraw consent for participation in any aspect of this trial at any time without affecting their routine diabetes care. All participants were advised to report any serious adverse events occurring throughout the trial as they would immediately be referred by the POs to their general practitioner.<sup>26</sup>

### Training

Initially, three POs were recruited at each site (n=24) from the existing diabetes healthcare providers (doctors/nurses/dietitians/health educators). POs received a 5-day bespoke training program facilitated by a health psychologist and public health specialist from the UK



and local PA experts. The training included recruitment procedures, outcome measurements, and delivering the 'MOVEdiabetes' intervention.<sup>26</sup> More importantly, it was agreed by all the POs that the dietitians would conduct the PA consultations.<sup>24</sup> This decision was based on discussions guided by insights from healthcare professionals, reported in one of the formative studies, on extending the role of dietitians to deliver PA services within diabetes primary care.<sup>24</sup>

#### Measures/assessment instruments

A multicomponent questionnaire was developed, reviewed and approved by the research group and ethics committee. Except for the sociodemographic data at baseline, all primary and secondary outcome data were collected at baseline and at 3 and 12 months.<sup>26</sup> The questionnaire included the following:

#### Sociodemographic data

Age, gender, marital status, education, and income were collected from the electronic health information system (HIS), and if data were missing they would be asked for it.

#### Metabolic and cardiovascular biomarkers

Weight, BMI ( $\text{kg}/\text{m}^2$ ), systolic and diastolic blood pressure (mm Hg), HbA1c (%), and lipid profile (mmol/L) (total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL), triglycerides (TGs)) were collected from the HIS in the health center.

#### Levels of PA and sitting time

Self-perceived PA (MET.min/week) was estimated via face-to-face interviews using the Global Physical Activity Questionnaire (GPAQ).<sup>29</sup> GPAQ is a 13-item PA questionnaire where levels of PA (MET.min/week) are estimated across work, travel and leisure domains.<sup>8</sup> Moreover, objective assessment of PA (steps/day) and sitting time (hours/day) was carried out in a subset of selected subjects (40%). Initially all participants were offered accelerometers (activPAL micro, an ~20 g professional PA monitor)<sup>30</sup> until the required numbers were reached. Application and removal of the accelerometers were performed in the health centers by the POs. The devices were programmed to continuously work for 7 days. They were wrapped in a plastic sleeve and then attached directly to the skin of the midline of the anterior aspect of the participant's right thigh using an adhesive pad and tube bandages to keep the activity monitor in place.<sup>31</sup> Participants were asked to adhere to wearing the device for 24 hours for 7 days and record their sleeping/waking time and removal of the device in a daily log given to them. Participants were strongly advised not to remove the device unless for swimming activities or if they experienced an allergic reactions, but to contact the POs in their respected health center if such an instance arose.

Self-efficacy,<sup>32</sup> social support,<sup>33</sup> and a trial-specific self-assessed general health questionnaire<sup>26</sup> were used

at baseline and at 12 months. The results from these secondary outcomes will be presented in parallel papers.<sup>26</sup>

#### Blinding

Except for the sociodemographic data at baseline, all measures were collected by specialist diabetes nurses who were blinded to the study objectives and group allocation. Owing to the nature of this study, the POs could not be blinded to study objectives; however, they were not involved in data entry and/or analysis.

#### The 'MOVEdiabetes' intervention group

All patients are advised on diet and weight management as part of routine care, but there are no requirements to focus on PA. The 'MOVEdiabetes' intervention was undertaken as personalized face-to-face consultations (maximum 20 min) by trained dietitians on three occasions (weeks 0, 4 and 8).<sup>26</sup> The consultations aimed to encourage participants to achieve 150 min of moderate-intensity or 75 min of vigorous-intensity PA (or a combination of the two) per week ( $\geq 600$  MET.min/week) at 12 months.<sup>26</sup> The consultations were based on multiple BCTs reported in the 'MOVEdiabetes' study protocol.<sup>36,34</sup> The content of the consultations is described in figure 1.

It is estimated that a step count of no less than 6000–7000 per day is required to achieve this goal.<sup>35</sup> Hence, all participants were given pedometers (Yamax Digi-Walker SW-200, Yamasa Tokei Keiki, Tokyo, Japan) to record their daily step counts for self-motivation and monitoring. Feedback on step counts was given within the PA consultation visits and/or discussed over the WhatsApp telephone application.

Notably, all participants receiving the intervention activated their telephone WhatsApp application and received monthly messages from the POs in their respected health center.<sup>36</sup> The messages were standardized to coincide with the international occasions/celebrations. These were hoped to motivate the participant to perform more PA (table 1). The messages were initially put in English and then translated to Arabic language to be sent to the participants. The content was reviewed and approved by the central and regional research ethical committees within the 'MOVEdiabetes' study protocol. POs initiated the WhatsApp groups, facilitated the conversations and monitored the group dynamics.

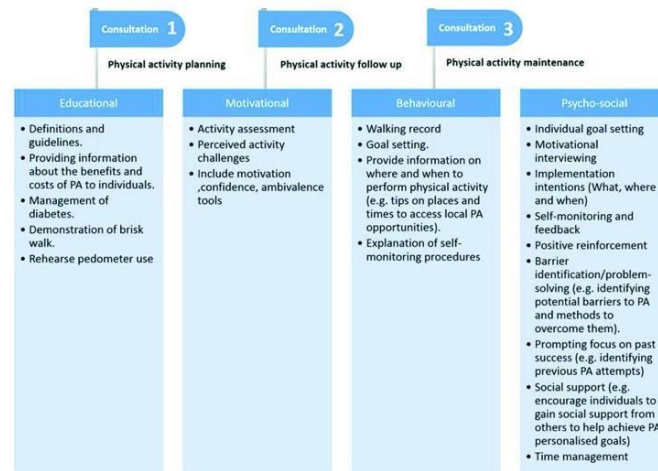
#### Comparison group

Participants allocated to the CG received no further study relevant contacts after 3 months measures until the end of the study where they had their final measurements recorded at 12 months follow-up.

#### Statistical analysis

The quality of the entered data was cross-checked by staff trained in quality assurance using checklists specific to the study in a sample of 10% of questionnaires selected at random. Data were entered into Epi Info V.7,<sup>37</sup> checked and cleaned prior to analysis. Entered data were transferred to IBM SPSS Statistics V.22.0 for Windows for





**Figure 1** Content of the face-to-face personalized physical activity (PA) consultations.

analysis according to the GPAQ protocol.<sup>8</sup> An intention-to-treat analysis was performed according to the last value carried forward imputation for missing data at 3 and/or 12 months, and a mean imputation procedure was done

where baseline data were missing. Descriptive statistics were expressed as proportions, mean (SD), and median (IQR) at the study group level.

**Table 1** Content of WhatsApp monthly messages

Month	Message	Special occasion if any
May	It is evident that regular physical activity of at least 150 min of moderate to vigorous intensity per week improves your body hemodynamics and blood glucose. Let's start slowly and build up the amount of time and intensity of the activity.	World Hypertension Day
June	Ramadhan is the month to fast from food and increase body movement, take this opportunity to increase your physical activity behavior.	Ramadhan
July	Include physical activity in your happy social and religious events.	Eid Al-Fitr
August	Breast feeding is good for mothers and babies especially if it is complemented with healthy lifestyle including physical activity.	World Breast Feeding Week
September	Pilgrim is the event that includes extensive physical activity. Increase your steps and keep on walking.	Eid Al-Adha
October	Physical activity is good for prevention and management of cancer so try to reach to 10 000 steps a day.	Breast Cancer Awareness Day
November	Celebrate the national day and have better diabetes control by increasing your daily walking steps.	Oman National Day and World Diabetes Day
December	Aging is an unavoidable risk factor, prevent disability by increasing you physical activity.	International Day of Persons with Disability
January	Start your new year with an aim to increase physical activity.	New Year
February	Being active physically is an important part of good health. 20-30 min of moderate to vigorous physical activity a day can help improve your health.	Healthy Lifestyle Awareness Day
March	Women are more vulnerable to be physically inactive. Keep moving to stay healthy, strong and pretty.	International Women's Day
April	It is never too late to start being physically active.	World Health Day
May	Being physically active supports diabetes prevention and management.	Ramadhan





Due to skewness of data obtained, a univariate analysis was done in two steps. Initially, for each outcome, differences at 3 and 12 months from baseline were calculated, and Mann-Whitney U tests used to estimate between-group differences (intervention vs comparison) and the Wilcoxon signed-rank test to estimate within-group differences. Then, a time trend for treatment effect was estimated from a generalized linear model (GLM).

Furthermore, the primary outcome was dichotomized to meeting the WHO PA recommendations, if MET.min/week values were  $\geq 600$ , and not meeting the recommendations for  $<600$  MET.min/week. GLM was used to determine the between-group difference in meeting the PA recommendations at 3 and 12 months independently.

Moreover, within the IG, a multivariate analysis was carried out to identify potential correlates for changes in PA at 12 months across the studied sociodemographic characteristics.

Accelerometer data of valid days, defined as 24 hours of wear per day with an allowance of no more than 4-hour removal time per day over the 7-day wear, with the monitor positioned in a dynamic axis orientation, were analyzed using a customized activPAL3 software.<sup>38</sup> Prior to analysis, daily hours of sleep were estimated from the participants' daily logs and eliminated from the outputs. The total number of steps per day and sitting time were then extracted from the accelerometer outputs, and between-group differences were explored.

#### Patient involvement

No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for design or implementation of the study. No patients were asked to advise on interpretation or writing up of results. However, plans to disseminate the results of the research to study participants and relevant patient community will be considered.

## RESULTS

### Recruitment, retention and attrition

Of the 441 participants who were screened for inactivity, 232 (53%) consented to participate in the study. In total 174 (75%) completed the study measurements at baseline and at 3-month and 12-month follow-up (110 IG vs 105 CG, and 82 IG vs 92 CG, respectively). Figure 1 presents the Consolidated Standards of Reporting Trials (CONSORT) flow chart that describes the progress of participants throughout the 12-month follow-up study.

Overall, out of 232 participants who provided consent, 227 (97.8%) completed the baseline measurements, 215 (92.7%) completed the 3-month follow-up measurements and 174 (75%) completed the final 12-month measurements. The reasons for attrition (IG  $n=40$ , CG  $n=18$ ) are presented in the CONSORT diagram (figure 2), and the most frequently reported reasons were feeling uncomfortable with the accelerometers (41%), joint pain

(14%), travel outside of Oman (12%), or being lost to follow-up without a reason being given (17%).

### Participants' sociodemographic and physiological characteristics

At baseline, more than half of the participants in both the intervention and comparison groups were women (64.5% and 54.1%, respectively), and the mean age (SD) of the total population was 44.2 (8.1) with a range of 22–68 years. The majority of the population (79.3%) were married, and half (50.9%) had completed their secondary education. Income was reported by 87.5% of the total population, of which more than half reported a moderate income of  $\leq 1000$  Omani rials/month. Additionally, more than half of the total population were employed, with a higher percentage in the intervention than in the comparison group (65.6% vs 50%, respectively). The two groups were similar in social status except for marital status (more married individuals in the CG vs IG) ( $p=0.03$ ) and employment status (more employed individuals in the IG vs CG) ( $p=0.02$ ) (table 2).

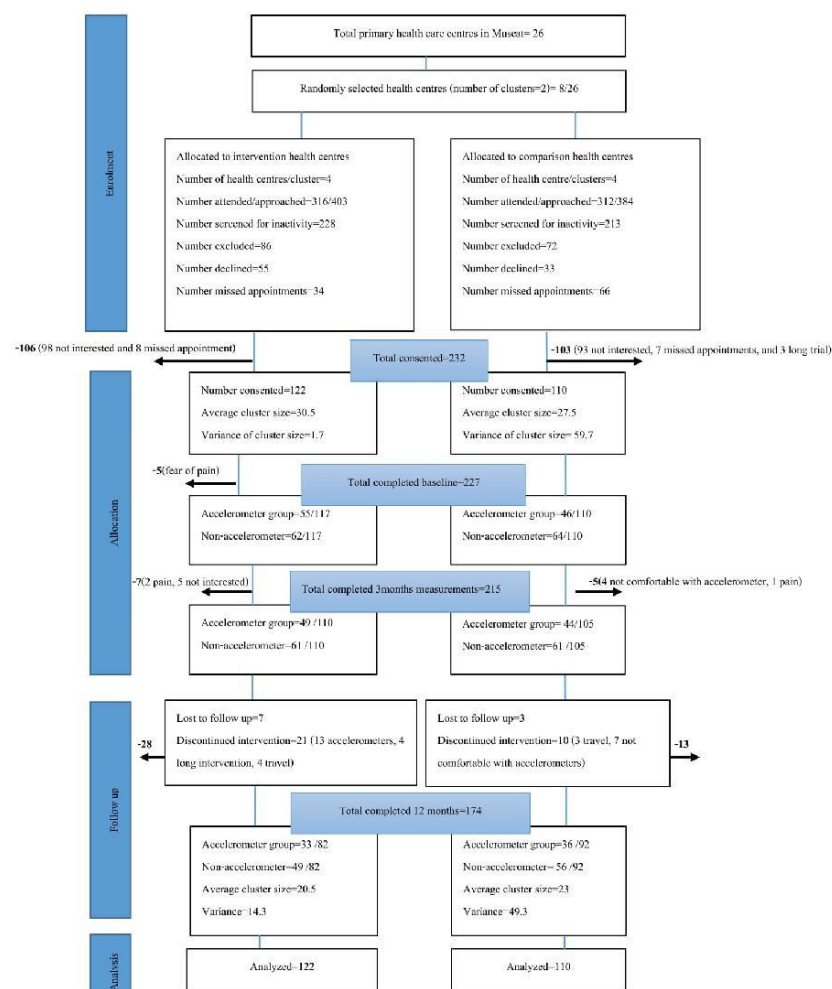
The mean (SD) duration of diabetes for the total population was 5.8 (3.7) years, and 77.2% of them reported comorbidities, mainly hypertension (45.3%) or hyperlipidemia (35.6%) or both (15%), for which all were on antihypertensives or statins (lipid-reducing drugs) or both accordingly. Most (81%) of the sample (84.5% IG vs 77.3% CG) were on oral hypoglycemic drugs, of which 13.8% also used insulin (9.8% IG vs 18.2% CG;  $p=0.07$ ) (table 2).

At baseline, the mean (SD) BMI was  $>30$  (8.3)  $\text{kg}/\text{m}^2$  in both groups. The mean systolic blood pressure (SBP) levels were within the target levels of  $<140$  mm Hg in both groups. The mean (SD) diastolic blood pressure (DBP) was significantly higher in the IG (83.2 (9.4) mm Hg) than in the CG (78.7 (14.4) mm Hg) ( $p=0.003$ ). The mean (SD) HbA1c in both groups was  $>7.0\%$  (8.1 (1.7)% IG vs 7.8 (1.7)% CG), indicating poor diabetes control according to the Omani diabetes management guidelines.<sup>39</sup> The average levels of total cholesterol and LDL, in both groups, were higher than the target limits. However, HDL and TG levels were all within target limits. There were no significant between-group differences in BMI, SBP, HbA1c, and lipid profile at baseline (table 3).

### Change in primary outcome (PA levels)

Overall, about two-thirds (68.9%) of the calculated PA level (MET.min/week) was attributed to leisure activity, followed by 28.6% by travel and 2.5% by work. The dominance of leisure activity as the main contributor to the overall PA levels was prominent in both groups at all measurement points.

At baseline there was no difference in median PA levels between the groups ( $p=0.08$ ). However, at 3-month and 12-month follow-up, the median (IQR) change in PA from baseline was significantly greater in the IG than in the CG at both time-points: +17% at 3 months (+140 (0–480) vs 0 (0–330) MET.min/week, respectively;  $p=0.04$ ) and +26%



**Figure 2** Consolidated Standards of Reporting Trials flow chart describing progress of participants through the 12-month follow-up study.

Clinical Care/Education/Nutrition			
<b>Table 2</b> Participants' sociodemographic characteristics in the treatment group			
Characteristics	Intervention group n=122 (52.6%)	Comparison group n=110 (47.4)	Total population n=232 (%)
Gender			
Male	56 (45.9)	39 (35.5)	95 (40.9)
Female	66 (54.1)	71 (64.5)	137 (59.1)
Age (years)			
Mean (SD)	43.5 (7.1)	45.1 (9.2)	44.2 (8.1)
≤44	65 (53.3)	48 (43.6)	113 (48.7)
>44	57 (46.7)	62 (56.4)	119 (51.3)
Marital status			
Currently unmarried	32 (26.2)	16 (14.5)	48 (20.7)
Currently married	90 (73.8)	94 (85.5)	184 (79.3)
Education			
≤Secondary	62 (50.8)	52 (47.3)	114 (49.1)
>Secondary	60 (49.2)	58 (52.7)	118 (50.9)
Income (Omani rials)*			
≤1000 per month	70 (57.4)	55 (50)	125 (53.9)
>1000 per month	41 (33.6)	37 (33.6)	78 (33.6)
Employment			
Currently unemployed	42 (34.4)	55 (50)	97 (41.8)
Currently employed	80 (65.6)	55 (50)	135 (58.2)
Mean duration of diabetes (SD)	6.4 (4.5)	5.3 (2.6)	5.8 (3.7)
≤5 years	63 (51.6)	52 (47.3)	115 (49.6)
>5 years	59 (48.4)	58 (52.7)	117 (50.4)
Comorbidities†			
No comorbidities	27 (22.1)	26 (23.6)	53 (22.8)
With comorbidities	95 (77.9)	84 (76.4)	179 (77.2)
Diabetes medication			
Diet only	7 (5.7)	5 (4.5)	12 (5.2)
Oral hypoglycemic drugs	103 (84.5)	85 (77.3)	188 (81.0)
Oral hypoglycemic+insulin	12 (9.8)	20 (18.2)	32 (13.8)

\*29 missing values due to reporting 'I don't know'.

†Presence of hypertension, hyperlipidemia, thyroid, or any other condition coinciding with diabetes registered in the health information system.

at 12 months (+80 (0–663) vs 0 (–7.5–361) MET.min/week, respectively;  $p=0.01$ ) (figure 3).

Additionally, figure 4 illustrates the steady increase in PA levels in both treatment groups, but in particular the significantly higher mean gain from baseline in the IG than in the CG at 12 months (+447.4 (95% CI 150.7 to 744.1) MET.min/week,  $p=0.003$ ) (table 2).

Within the IG, the gain in PA levels at 12 months was significantly associated with high education (+500 MET.min/week,  $p=0.04$ , 95% CI 33.0 to 1144.4) and high income (+600 MET.min/week,  $p=0.02$ , 95% CI 127.7 to 1278.6).

Despite no significant differences at baseline, the odds of meeting the WHO PA recommendations were significantly higher, by 1.8 ( $p=0.04$ , 95% CI 1.1 to 3.1) and 1.9

( $p=0.02$ , 95% CI 1.2 to 3.3) times, in the IG compared with the CG at 3 and 12 months, respectively (table 4).

### Secondary outcomes

#### Objectively measured step counts/day

Around half (48%) ( $n=59$ ) of the participants in the IG vs 40% ( $n=44$ ) in the CG used accelerometers at baseline. Overall, 69 participants (67%) had completed accelerometer use at both baseline and 12 months (33 in the IG vs 36 from the CG). The average (SD) number of valid days (minimum of 4 valid days) at baseline and at 3 and 12 months was 5.7 (1.0) ( $n=45$ ), 5.3 (1.2) ( $n=38$ ) and 5.3 (1.3) ( $n=28$ ) in the IG, and 5.9 (1.0) ( $n=39$ ), 5.4 (0.93) ( $n=32$ ) and 5.9 (1.1) ( $n=30$ ) in the CG, respectively.





**Table 3** Changes in primary (PA (MET.min/week) and sitting time (hours/day)) and secondary outcome measures from baseline to 3 and 12 months, by treatment group

Measures	Baseline			3 months			12 months			Between-group difference, p values	
	n	Mean (SD)	n	Mean (SD)	Difference from baseline	n	Mean (SD)	Difference from baseline	n	Mean (SD)	Difference from baseline
<b>Primary outcome</b>											
Self-reported PA average MET.min/week											
Intervention	117	200 (342)	110	591 (105.4)	+390 (97.8)	82	832 (151.5)	+631 (146.1)	82	+246 (39.2 to 452.6)	+447 (150.7 to 744.1)
Comparison	110	201 (235)	105	345 (368)	+144 (329)	92	385 (52.4)	+183 (529)	92	<b>0.02*</b>	<b>0.003*</b>
<b>Secondary outcomes</b>											
Objectively measured steps/day											
Intervention	59	4752 (1058)	44	5912 (1620)	+1161 (1617)	33	7034 (2408)	+2282 (2635)	33	+43 (−544 to 630)	+757 (18.4 to 1531)
Comparison	44	5932 (5413)	39	5870 (1369)	−62.1 (5270)	36	6278 (1270)	+346 (5297)	36	0.9	<b>0.049*</b>
Objectively measured sitting time hours/day											
Intervention	59	13.4 (2.4)	44	12.4 (1.9)	−1.1 (1.6)	33	12.2 (2.2)	−1.2 (1.7)	33	−1.3 (−2.2 to −0.6)	−1.5 (−2.4 to −0.7)
Comparison	44	13.7 (1.0)	39	13.6 (1.2)	0.2 (0.8)	36	13.7 (1.4)	+0.1 (1.2)	36	<b>&lt;0.001*</b>	<b>&lt;0.001*</b>
Weight											
Intervention	117	89.6 (20.5)	110	88.8 (20.5)	−0.8 (2.6)	82	85.9 (16.8)	−3.7 (10.4)†	82	+4.0 (−1.2 to 9.2)	−2.2 (−2.4 to 6.9)
Comparison	110	85.6 (20.5)	105	84.8 (20.2)	−0.7 (3.7)	92	83.7 (19.5)	−1.7 (6.2)	92	0.1	0.3
BMI (kg/m <sup>2</sup> )											
Intervention	117	33.8 (7.9)	110	33.8 (6.8)	−0.001 (4.5)	82	31.8 (4.5)	−0.03 (4.5)†	82	+0.7 (−1.2 to 2.5)	−0.6 (−1.9 to 0.8)
Comparison	110	33.1 (8.7)	105	33.2 (7.8)	+0.08 (5.3)	92	32.4 (6.2)	+0.08 (5.3)	92	0.49	0.40
HbA1c (%)											
Intervention	117	8.1 (1.7)	110	8.1 (1.2)	+0.1 (1.200)	82	7.7 (1.4)	−0.4 (1.8)†	82	+0.3 (−0.1 to 0.7)	+0.2 (−0.2 to 0.5)
Comparison	110	7.8 (1.7)	105	7.8 (1.6)	+0.1 (0.817)	92	7.5 (1.3)	−0.3 (1.5)	92	0.11	0.30
Systolic blood pressure (mm Hg)†											
Intervention	117	128 (9.0)	110	126 (12.1)	−1.9 (13.0)	82	128 (5.7)	−0.6 (9.4)	82	−3.8 (−6.7 to −0.9)	−1.8 (−3.5 to −0.1)
Comparison	110	129 (10.7)	105	130 (9.9)	+0.9 (8.1)	92	129 (7.5)	+0.2 (6.6)	92	<b>0.008*</b>	<b>0.04*</b>
Diastolic blood pressure (mm Hg)†											
Intervention	117	83 (9.4)	110	82 (6.6)	−1.1 (9.3)	82	80 (4.2)	−3.1 (9.4)	82	+0.9 (−1.0 to 2.9)	−1.6 (−2.6 to −0.7)
Comparison	110	78.7 (14.4)	105	81.1 (8.5)	+0.5 (13.1)	92	81.7 (5.4)	+3.0 (0.7)	92	0.36	<b>0.001*</b>
Fasting cholesterol (mmol/L)†											

Continued

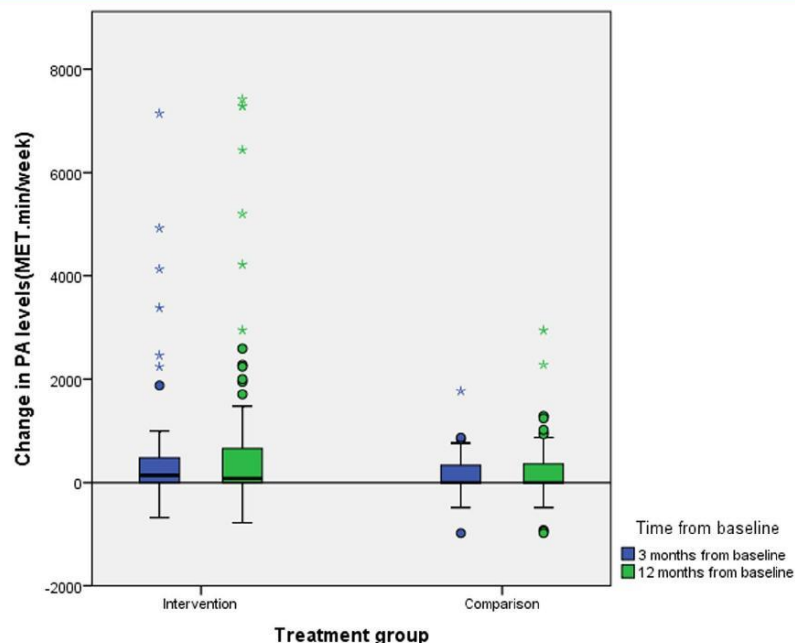
Table 3 Continued

Measures	Baseline			3 months			12 months			Between-group difference, p values	
	n	Mean (SD)	n	Mean (SD)	Difference from baseline	n	Mean (SD)	Difference from baseline	n	Mean (SD)	Difference from baseline
Intervention	117	5.0 (1.2)	110	4.8 (0.7)	-0.2 (0.9)	82	4.5 (1.0)	-0.5 (1.1)	82	4.5 (1.0)	-0.5 (1.1)
Comparison	110	4.9 (1.0)	105	4.9 (0.9)	-0.1 (0.7)	92	4.6 (0.8)	-0.3 (0.9)	92	4.6 (0.8)	-0.3 (0.9)
HDL (mmol/L) <sup>‡</sup>											
Intervention	117	1.6 (1.2)	110	1.6 (0.7)	-0.15 (1.2)	82	1.9 (0.9)	-0.04 (1.5)	82	1.9 (0.9)	-0.04 (1.5)
Comparison	110	1.8 (1.5)	105	1.6 (1.1)	-0.01 (1.3)	92	1.8 (0.8)	+0.3 (1.6)	92	1.8 (0.8)	+0.3 (1.6)
LDL (mmol/L) <sup>‡</sup>											
Intervention	117	2.9 (1.0)	110	2.9 (0.9)	-0.1 (0.5)	82	2.4 (0.9)	-0.3 (0.9)	82	2.4 (0.9)	-0.3 (0.9)
Comparison	110	3.0 (0.9)	105	2.9 (0.9)	-0.1 (0.9)	92	2.6 (0.9)	-0.7 (1.2)	92	2.6 (0.9)	-0.7 (1.2)
TG (mmol/L) <sup>‡</sup>											
Intervention	117	1.4 (0.6)	110	1.4 (0.8)	+0.1 (0.7)	82	1.3 (0.5)	-0.09 (0.3)	82	1.3 (0.5)	-0.09 (0.3)
Comparison	110	1.5 (0.9)	105	1.6 (1.0)	+0.04 (0.8)	92	1.6 (1.0)	+0.05 (0.7)	92	1.6 (1.0)	+0.05 (0.7)

\*Bold format = significant values at P&lt;0.05.

<sup>†</sup>Significant within-group difference at 12 months from baseline using non-parametric test (Wilcoxon signed-rank test).<sup>‡</sup>All target values are based on the Oman diabetes mellitus management guidelines (2015): BMI 18.5–25 kg/m<sup>2</sup>, HbA1c ≤7%, SBP/DBP <140/80 mm Hg, cholesterol <5.0 mmol/L, HDL >1.0 mmol/L.<sup>§</sup>LDL <2.6 mmol/L, TG <1.7 mmol/L.<sup>||</sup>LDL <2.6 mmol/L, TG <1.7 mmol/L.

BMI, body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein; HbA1c, glycated haemoglobin; LDL, low-density lipoprotein; PA, physical activity; SBP, systolic blood pressure; TG, triglycerides.



**Figure 3** Change in physical activity (PA) levels from baseline at 3 and 12 months by treatment group. MET, Metabolic Equivalent.

The average number of steps/day initially increased in the IG only at 3 months, thereafter increasing in both groups, such that the overall increase from baseline at 12 months was significantly greater in the IG than in the CG (table 4). Overall at 12 months the average steps/day was +757 steps/day higher in the intervention compared with the comparison group ( $p=0.05$ , 95% CI -18 to +1531) (table 3).

#### Sitting time

Sitting time (hours/day) was found to change from 13.1 (2.4) to 12.2 (1.9) at 3 months to 12.2 (2.2) at 12 months within the IG versus a change from 13.7 (1.0) at baseline to 13.6 (1.2) at 3 months to 13.7 (1.4) at 12 months within the CG. Moreover, there was a significantly greater reduction in sitting time (hours/day) in the IG versus CG at both 3 and 12 months, by -1.3 (95% CI -2.2 to -0.6) and -1.5 (95% CI -2.4 to -0.7) hours per day, respectively (table 3).

#### Weight, BMI, HbA1c, BP, and lipid profile

Table 3 illustrates the lack of any between-group differences in changes in weight, BMI or HbA1c. However, there were significantly greater reductions in the IG compared with CG in SBP by -3.8 (95% CI -6.7 to -0.9) mm Hg ( $p=0.008$ ) at 3 months and -1.8 (95% CI -2.6 to -0.7) mm Hg ( $p=0.04$ ) at 12 months, and in DBP by -1.6

(95% CI -2.6 to -0.7) mm Hg ( $p=0.001$ ) at 12 months. Additionally, a significantly greater reduction in TG levels of -0.3 (95% CI -0.5 to -0.08) mmol/L ( $p=0.006$ ) was observed in the IG versus CG.

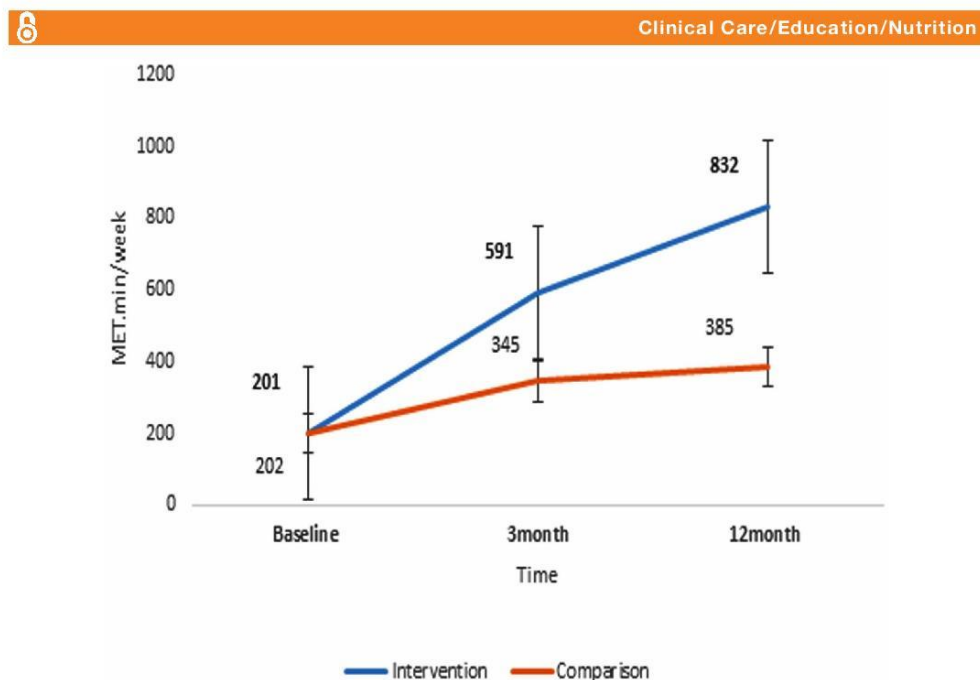
Nonetheless, despite no between-group differences in change in weight, BMI and HbA1c, significant within-group differences for median weight ( $p\leq 0.001$ ), BMI ( $p\leq 0.001$ ) and HbA1c ( $p=0.03$ ) were found in the IG between baseline and 12 months.

#### Adverse events

Except for discomfort from accelerometer use, no adverse events reported by participants were considered to be related to participation in the trial in neither the IG nor the CG.

#### DISCUSSION

The current study showed that the multicomponent 'MOVEdiabetes' intervention, delivered by trained dietitians, was effective in increasing PA levels in physically inactive adults with T2D within a local diabetes primary care setting at 12 months. The objective accelerometer data also indicated a favorable increase in average number of steps/day in the IG. Similarly, objectively measured sitting time was reduced in the IG by -1.5 hours/day more than in the CG.



**Figure 4** Mean (SE) change in mean physical activity levels (MET.min/week) in the treatment groups over 12 months. MET, Metabolic Equivalent.

Importantly, despite no significant changes in the metabolic outcomes (weight, BMI and HbA1c), the intervention showed favorable cardiovascular long-term outcomes,<sup>2</sup> namely in reducing systolic and diastolic blood pressure and TGs at 12 months.

#### Strengths and weaknesses of this study

This study makes a significant contribution to the current limited literature on translational research on effective PA interventions internationally and in particular in the Arab world.<sup>4</sup>

Strengths of the current study demonstrate the ability of existing health professionals, namely dietitians, to extend their roles and deliver the intervention in a relevant clinical setting. Moreover, the use of physiological

data from patients' routine electronic medical records enabled the reporting of clinically relevant data.

This is the first trial to use accelerometers within the local clinical diabetes setting in Oman. Despite the complexity of data from the accelerometers pertaining to dropout and non-compliance to the 24-hour wear protocol, changes in average steps/day and sitting time were in favor of the IG at 12 months. This finding supports the positive effects of the 'MOVEdiabetes' intervention on PA levels in the IG versus CG obtained from the self-reported questionnaire.

It should be noted that the trial sample size was calculated on the basis of detecting changes in the self-reported PA questionnaire, not the accelerometers' data.

**Table 4** Odds of meeting PA recommendation at baseline and at 3 and 12 months between the treatment groups

	Baseline (%)			3 months (%)			12 months (%)		
	n (%)	OR	95% CI (p values)	n (%)	OR	95% CI (p values)	n (%)	OR	95% CI (p values)
Intervention	13 (10.7)	1.7	0.6 to 4.6	46 (37.7)	1.8	1.1 to 3.1	52 (42.6)	1.9	1.2 to 3.3
Comparison	7 (6.4)	Ref	(0.3)	28 (25.5)	Ref	(0.04)	31 (28.2)	Ref	(0.02)

PA, physical activity; Ref, reference.





Moreover, despite the fact that the aim of the trial was not to validate the tools, limitations of the self-reported PA data including the possibility of false reporting cannot be excluded.<sup>40</sup> Hence, further exploration may be required to validate the subjective PA measurement tools (GPAQ), investigate reasons for non-adherence and identify ways to improve compliance to accelerometer use.

Moreover, consistent with the evidence on the dominance of leisure time PA,<sup>41</sup> the results from this study indicated the importance of leisure time activity in the overall increase in PA levels. However, a focus on the other PA domains (work and travel), where inactivity levels are more prominent, may be considered in further studies, especially given that more than half of the participants in both groups were employed. This could include interventions to increase PA and reduce sitting time at workplaces via walk and talk meetings, marked worksite walking paths, standing desks and interrupted screen time programs.<sup>42</sup>

#### Strengths and weakness in relation to other studies

The intervention used in this trial included support provided via WhatsApp messages. To our knowledge, this is the first study to integrate such technology-based approach as a long-term support tool within a PA intervention study in Oman. It is possible that this approach could escalate trust between participants and POs in their respected health centers that facilitated sharing of information, and seeking support and feedback when needed.<sup>43</sup> However, a study in Spain reported minor effects from WhatsApp-based interventions to promote PA training compared with face-to-face interventions.<sup>44</sup> These results could be affected by cultural differences or the short study duration (10 weeks) and/or small sample size ( $n=32$ ) in the latter study. Therefore, further research is needed on the use of WhatsApp and/or any other texting applications in promoting PA in clinical settings (alone and as part of an intervention design).

Notably, similar to other studies, high education<sup>45</sup> and high income<sup>46</sup> were associated with the long-term increase in PA levels within the IG. This finding may be linked to greater awareness of health issues and greater purchasing capacity for resources, such as<sup>46</sup> pedometers, watches, treadmills or gym memberships, which could facilitate positive PA behavior change in higher socioeconomic groups.<sup>47</sup>

It is notable that throughout the study period, sitting time was high ( $\geq 10$  hours/day), exceeding the time reported in other studies in Oman.<sup>48</sup> This is an important finding because sitting more than 8 hours/day increases the risk of all-cause mortality (even among individuals achieving the recommended 150 min/week of PA).<sup>49</sup> It is possible that timing of data collection, population characteristics and cultural norms may have been different across those studies that have investigated this relationship. As such, addressing long sitting time patterns is required in further studies.<sup>30</sup>

The results from this study indicate a relatively small effect size; however, short-term and long-term odds of meeting the PA recommendation of  $\geq 600$  MET.min/week were significantly higher in the intervention versus comparison group (table 4), indicating potential clinical benefits of the 'MOVEdiabetes' intervention on general health. Other benefits related to body composition were not explored in this study; however, the results showed positive effects of the 'MOVEdiabetes' intervention on lowering blood pressure and TG levels, indicating possible cardioprotective benefits.

The lack of a significant impact on the secondary outcomes, namely weight, BMI and HbA1c, is not unexpected given the intervention focused on PA alone (because usual care already provided advice on diet or weight management). More importantly, this result may be attributed to limited power to detect an intervention effect. Future adequately powered studies are required to better understand the impact of this intervention on secondary outcomes, including the biomedical, metabolic and cardiovascular markers.

#### Implications of the study for clinicians and policy makers

Given the rising trends of diabetes and physical inactivity in Oman, this study provides a potential and pragmatic platform for recommendations for greater integration of PA in the management of diabetes. The multidisciplinary approach applied in this intervention provided potential solutions for perceived barriers by health professionals on promoting PA, namely lack of time and frequent staff turnover.<sup>24</sup> Although dietitians were responsible for delivering the PA consultations, diabetes doctors and nurses were all involved to reinforce the same PA messages to the participants. Moreover, with respect to the PA consultation guidelines reported in the literature,<sup>19 50 51</sup> the guidelines on the personalized 'MOVEdiabetes' PA consultations within the current study could be further developed for consideration in future similar interventions in the Arab world. Equally important, similar to an online training program for healthcare professionals on PA,<sup>52-54</sup> the PA training linked to this study for the healthcare professionals could be adapted at regional and central health administrative levels to be used in future PA training activities.

#### Unanswered questions and future research

A process analysis to assess the feasibility, appropriateness and suitability of roll-out of this intervention is yet to be undertaken. Further studies are required to ensure that the increase in PA levels is sustainable. Moreover, although this trial was integrated within routine care, future cost analysis may be required to highlight any additional cost-benefit.

#### CONCLUSION

The 'MOVEdiabetes' intervention (face-to-face PA consultation delivered by a trained dietitian, with use of pedometers and WhatsApp telephone application for





self-monitoring and support) was effective in increasing short-term and long-term PA, reducing sitting time and increasing the likelihood of meeting the WHO PA recommendations in adults with T2D attending their routine diabetes primary care clinics over 12 months. Additionally, despite no significant impact on weight, BMI and HbA1c, the intervention showed potentially protective cardiovascular effectiveness, namely in reducing blood pressure and TG levels.

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**Patient consent** Obtained.

**Ethics approval** Omani Research and Ethical Review and Approve Committee in the Ministry of Health.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** Data available on reasonable request and approval from the Oman Ministry of Health.

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## Appendix 7.2: Agenda for the “MOVEdiabetes” training



### Physical activity behaviour change consultations

Holiday Inn Hotel, Muscat, Oman  
10-14 April 2016

Day 1-3: 10-12 April, Tuesday - Theme1: Physical activity in health		
07:30-08:00	Participants' Registration every day	
08:00-08:20	Participants' Introduction & Expectations every day Hosting team	Thamra
Day 1		
	Short video and Pre-test	
10:20-13:00	Physical activity – Definitions and recommendations	Abdulhamid
14:30-15:30	Physical activity – Benefits	Abdullah Alfarsi
	Wrap Up: Daily Evaluation, Recommendation, House Keeping and introduction to host team	
Day 2		
10:00- 11:30	Physical activity – Measurements	Abdulhamid
11:30-12:30	Group work- using questionnaires, pedometer and accelerometer	Thamra
Day 3		
10:20-13:00	Barriers to performing PA	
13:30-14:00	Interventions to promote PA	
	Wrap Up: Daily Evaluation, Recommendation, House Keeping and introduction to host team	
14:00-14:30	Lunch break	
Day 4: 13 April, Wednesday - Theme2: behaviour change consultations		
08:00-08:30	Recap & Introduction of the day	Thamra
08:30-09:30	Theories of behaviour change	Mary
09:30-10:00	Behaviour change techniques	Mary
10:00-10:30	Coffee Break	Mary
10:30-11:30	Physical activity consultations	Mary
11:30-12:30	Physical activity consultations-lessons learned	Mary
12:30-13:30	Role play	Mary
13:30-14:00	Wrap Up: Daily Evaluation, Recommendation, House Keeping and introduction to host team	
14:00 –14:30	Lunch break	
Day5: 14 April, Thursday - Theme3: intervention protocol		
08:00-08:30	Recap & Introduction of the day	
08:30-09:30	Physical activity interventions in primary health care	Mary
09:30-10:00	Intervention protocol	Thamra
10:00-10:30	Coffee Break	
10:30-12:30	Role play-PAC	Mary
12:30-13:30	Role play-PAC	Mary
13:30-14:30	Certificates, evaluation & Lunch break	



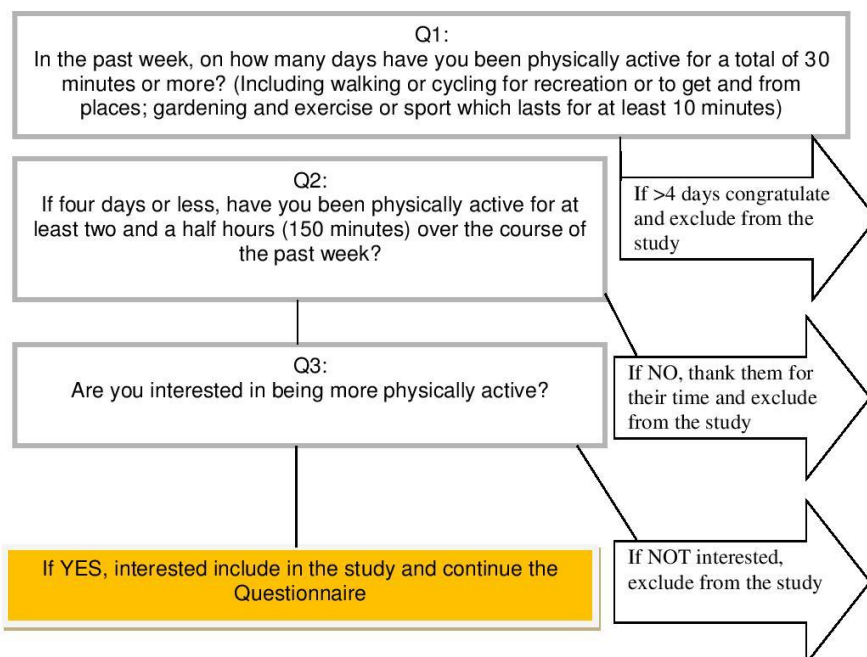


## Appendix 7.3: The “MOVEdiabetes” questionnaire (in English and Arabic languages)



### “MOVEdiabetes” A Trial to Promote Physical Activity for Adults with Type 2 Diabetes in Primary Health Care in Oman

#### Step 1: Screening for inactive behaviour



#### Step 2: screening for eligibility criteria

Before starting make sure that your client (by the interviewer):

- **Is a patient with type 2 diabetes.**
- **Is 18-60 years old.**
- **Has had no less than 6months follow up in the diabetes clinic in the health center.**
- **Has read the information sheet and signed the consent form.**

Day of the interview D/ M/ Y-----  
---

Time commenced----- :---

Interviewers name:

**Step 3: Demographic data:**

## 1- Marital status

1. Never married
2. Currently married
3. Separated / Divorced
4. Widowed

## 2- Education

1. Don't read or write
2. Less than primary school
3. primary school completed
4. Preparatory
5. Secondary school completed
6. College completed
7. University completed
8. Post graduate degree completed

## 3- Household Income per month (income of all household members, and from all sources (including benefits))

1. < 500 Omani rials
2. 500 - <1000
3. 1000 - <1500
4. 1500 - <2000
5. >=2000
77 Don't Know
88 Prefer not to answer

## 4- Working status (you can select more than one answer)

1. Government employee--- Job
2. Non-government employee ---Job
3. Self-employed
4. Unemployed
• Student: Full-time
• Student: Part-time
• Retired
• House wife
88Prefer not to answer

**Step 4: Medical history**

1. Date of birth: D/ M/ Y: \_\_\_\_\_ age  
: \_\_\_\_\_

2. Gender:

1- Male

2- Female

3. Year of diagnosis of diabetes : \_\_\_\_\_

4. Other medical (co-existing) chronic conditions or complications of diabetes:

1.	Cardiovascular disease ----specify (e.g: hypertension, heart failure, coronary heart disease, cardiomyopathies, stroke)
2.	Renal disease -----specify (e.g: renal failure, high GFR)
3.	Thyroid disease----specify (e.g: hypothyroid, hyper thyroid , cancer , thyroid nodule)
4.	Musculoskeletal ---specify (e.g: osteoarthritis)
5.	Eye -----specify (e.g: retina problems, glaucoma, cataract)
6.	Foot & Skin---- specify (e.g: amputation, ulcer)
7.	Other ----- specify
8.	None

5. Please list your current medications, doses and date commenced:

Name of medicine	Dose

6. Please list the most recent measurements recorded:

	Measurement	Date of recording
Weight (kg)		
Height (cm)		
BMI (kg/m <sup>2</sup> )		
Waist circumference		
Waist Hip Ratio (WHR) if available		
Glycated Hb		
Fasting glucose level		
Systolic BP (mm Hg)		
Diastolic BP (mm Hg)		
Total cholesterol		
HDL		
LDL		
Triglycerides		

7.	How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours : <input type="text"/> : <input type="text"/> minutes          hrs          mins
8.	<b>How much time do you spend at work in a regular day?</b>	<b>Hours : <input type="text"/> : <input type="text"/> minutes          hrs          mins</b>
<b>Travel to and from places (including to and from work)</b>		
The next questions exclude the physical activities at work that you have already mentioned. Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to place of worship.		
9.	<b>Do you walk or use a bicycle (<i>pedal cycle</i>) for at least 10 minutes continuously to get to and from places?</b>	<b>1. Yes</b>  <b>2. No          <i>If No, go to Q 12</i></b>
10.	In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days <input type="text"/>
11.	How much time do you spend walking or bicycling for travel on a typical day?	Hours : <input type="text"/> : <input type="text"/> minutes          hrs          mins
<b>Recreational activities</b>		
<b>The next questions exclude the work and transport activities that you have already mentioned. Now I would like to ask you about sports, fitness and recreational activities (<i>leisure</i>).</b>		
12.	<b>Does your recreational time involve more of sitting/ lying down or less than 10 minutes continues Physical activity (<i>inactive/sedentary</i>)?</b>	<b>1. Yes</b>  <b>2. No</b>
13.	Do you do any vigorous-intensity sports, fitness or recreational ( <i>leisure</i> ) activities that cause large increases in breathing or heart rate [ <i>like running or football</i> ] for at least 10 minutes continuously?	1.Yes 2.No <b><i>If No, go to Q 16</i></b>
14.	In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational ( <i>leisure</i> ) activities?	Number of days <input type="text"/>



**Step 5: Physical activity data from the WHO (GPAQ):**

Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person. Think first about the time you spend doing work (paid or unpaid) e.g. study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment.

In answering the following questions:

- '**Vigorous-intensity**' activities require hard physical effort and cause large increases in breathing or heart rate.
- '**Moderate-intensity**' activities require some physical effort and cause noticeable increases in breathing or heart rate.

Questions		Response
<b>Activity at work (excluding travel to and from work)</b>		
1.	<b>Does your work involve more of sitting or a continuous less than 10 minutes standing or walking (inactive/sedentary)?</b>	1. Yes 2. No
2.	Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate <i>[like carrying or lifting heavy loads, digging or construction work]</i> for at least 10 minutes continuously?	1. Yes 2. No <b><i>If No, go to Q 5</i></b>
3.	In a typical week, on how many days do you do vigorous-intensity activities as part of your work?	Number of days <input type="text"/>
4.	How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours : <input type="text"/> : <input type="text"/> minutes      hrs      mins
5.	Does your work involve moderate-intensity activity that causes noticeable increases in breathing or heart rate such as brisk walking <i>[or carrying light loads]</i> for at least 10 minutes continuously?	1. Yes 2. No <b><i>If No, go to Q 8</i></b>
6.	In a typical week, on how many days do you do moderate-intensity activities as part of your work?	Number of days <input type="text"/>

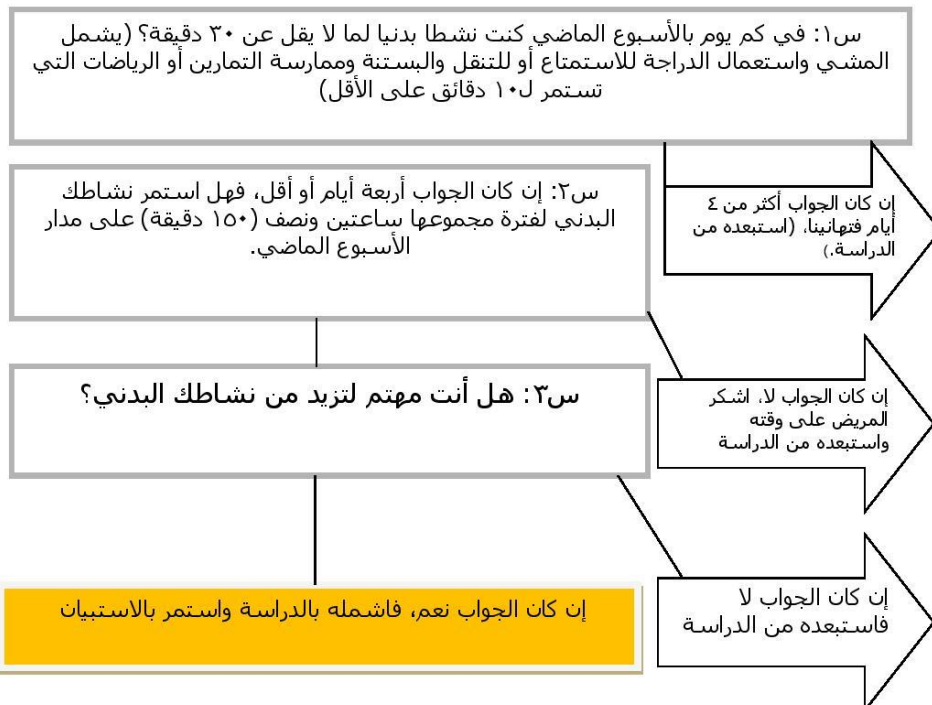
15.	How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	Hours : <input type="text"/> : <input type="text"/> minutes          hrs          mins
16.	Do you do any moderate-intensity sports, fitness or recreational ( <i>leisure</i> ) activities that cause noticeable increases in breathing or heart rate for at least 10 minutes continuously?	1. Yes 2. No <b><i>If No, go to Q 19</i></b>
17.	In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational ( <i>leisure</i> ) activities?	Number of days <input type="text"/>
18.	How much time do you spend doing moderate intensity sports, fitness or recreational activities on a typical day?	Hours : <input type="text"/> : <input type="text"/> minutes          hrs          mins
<b>Sitting time</b> <b>The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent [sitting at a desk, sitting with friends, travelling in car, bus, train, reading, playing cards or watching television], but do not include time spent sleeping.</b>		
19.	How much time do you usually spend sitting or reclining on a typical day?	Hours : <input type="text"/> : <input type="text"/> minutes          hrs          mins
20.	How much time do you usually spend sitting or reclining at work?	Hours : <input type="text"/> : <input type="text"/> minutes          hrs          mins
21.	How much time do you usually spend sitting or reclining on travel?	Hours : <input type="text"/> : <input type="text"/> minutes          hrs          mins
22.	How much time do you usually spend sitting or reclining at home (watching TV/socializing(Qahwa)/sewing and house work?	Hours : <input type="text"/> : <input type="text"/> minutes          hrs          mins

Time :



## دراسة "MOVEdiabetes" لترويج النشاط البدني في البالغين من المصابين بالنوع الثاني من السكري في مراكز الرعاية الصحية الأولية في عمان

### الخطوة الأولى: الكشف عن السلوك غير النشط



### الخطوة ٢: الكشف عن معايير الدخول للدراسة

قبل البدء يجب على الذي يجري المقابلة أن يتأكد من أن المرشح للدراسة:

- مصاب بالنوع الثاني من السكري
- عمره بين ١٨-٦٥ سنة
- مسجل في عيادة السكري بالمركز الصحي
- قرأ ورقة المعلومات ووقع بالموافقة عليها

تاريخ المقابلة: يوم/شهر/ سنة ----- وقت البدء: -----  
اسم القائم بالمقابلة:

## الخطوة ٣: البيانات الديموغرافية

١- الحالة الاجتماعية:

١. لم يسبق له/لها الزواج
٢. متزوج/متزوجة حالياً
٣. منفصل/مطلق
٤. أرمل/أرملة

٢- المستوى التعليمي:

١. لا يقرأ ولا يكتب
٢. أقل من مستوى الدراسة الابتدائية
٣. أكمل الدراسة الابتدائية
٤. الدراسة الإعدادية
٥. أكمل الدراسة الثانوية
٦. أكمل الدراسة بالكلية
٧. أكمل الدراسة بالجامعة
٨. أكمل الدراسات العليا

٣- الدخل المالي الشهري (الدخل لكل أفراد العائلة ومن كل المصادر بما يشمل التقاعد والضمان)

١. أقل من ٥٠٠ ريال عماني
٢. بين ٥٠٠ إلى أقل من ألف ريال عماني
٣. بين ألف إلى أقل من ١٥٠٠ ريال عماني
٤. بين ١٥٠٠ إلى أقل من ٢٠٠٠ ريال عماني
٥. ٢٠٠٠ ريال عماني أو أكثر
٧٧. لا يعلم
٨٨. يفضل عدم الإجابة على السؤال

٤- العمل (يمكنك اختيار أكثر من حالة واحدة)

١. لديه عمل- موظف حكومي
٢. لديه عمل- موظف غير حكومي
٣. أعمال خاصة
٤. غير عامل
طالب: بدوام كامل
طالب بدوام جزئي
متقاعد
للنساء: ربة منزل
٨٨: يفضل عدم الإجابة على السؤال

	مستوى السكر بالدم أثناء الصوم
	ضغط الدم الانقباضي (مم زئبق)
	ضغط الدم الانبساطي (مم زئبق)
	مستوى الكوليسترول بالدم
	HDL
	LDL
	ثلاثي الجلسرايد

#### الخطوة ٥: بيانات النشاط البدني من منظمة الصحة العالمية (GPAQ):

بعد ذلك سأقوم بتوجيه أسئلة لك عن الوقت الذي تقضيه في ممارسة مختلف أنواع النشاط البدني خلال أسبوع اعتيادي، يرجى الإجابة على الأسئلة حتى وإن كنت لا تعتبر نفسك شخصا نشطا بدنيا، فكر أولا في الوقت الذي تصرفه في العمل (سواء كان مدفوع الأجر أم لا) مثل الدراسة أو التدريب والأعمال المنزلية والبستنة والصيد أو البحث عن وظيفة. وعند الإجابة على الأسئلة:

- فإن الفعاليات التي تتطلب نشاطا شديدا هي التي تتطلب جهدا بدنيا كبيرا وتتسبب في ارتفاع كبير في معدلات التنفس ونبضات القلب.
- الفعاليات التي تتطلب نشاطا معتدلا هي التي تتطلب جهدا بدنيا إلى حد ما وتتسبب في ارتفاع ملحوظ بالتنفس ونبضات القلب.

الأسئلة	الاستجابات
نشاط العمل (باستثناء السفر من وإلى العمل)	
١. هل يشمل عملك ممارسة نشاط بدني شديد بما يتسبب في ارتفاع كبير بمعدل التنفس ونبضات القلب [مثل حمل أشياء ثقيلة أو الحفر أو أعمال البناء] لفترة ١٠ دقائق متصلة على الأقل؟	١- نعم ٢- لا
٢. في خلال أسبوع اعتيادي، كم مرة تمارس نشاطا بدنيا شديدا كجزء من عملك؟	عدد الأيام
٣. كم الوقت الذي تقضيه وأنت تمارس النشاط البدني الشديد في العمل خلال يوم واحد	الدقائق: الساعات دقائق : ساعات

## الخطوة ٤: التاريخ الطبي

- ١- تاريخ الميلاد: يوم/شهر/سنة \_\_\_\_\_ العمر: \_\_\_\_\_
- ٢- الجنس: ١- ذكر ٢- أنثى
- ٣- السنة التي تم تشخيص السكري بها: \_\_\_\_\_
- ٤- الحالات الطبية الأخرى بالمريض أو مضاعفات السكري التي لديه:

١.	أمراض القلب الوعائية—اذكر بالتفصيل (مثل ارتفاع ضغط الدم، الفشل القلبي، أمراض القلب التاجية، اعتلال عضلة القلب، الجلطة الدماغية)
٢.	أمراض الكلى—اذكر بالتفصيل (مثل الفشل الكلوي، ارتفاع معدل ترشح الكبيبي (GFR))
٣.	أمراض الغدة الدرقية—اذكر بالتفصيل (فرط نشاط الدرقية، هبوط الدرقية، السرطان، عقد الدرقية)
٤.	أمراض العظام والعضلات—اذكر بالتفصيل (فصال عظمي)
٥.	أمراض العيون—اذكر بالتفصيل (مشاكل الشبكية، النزول الأسود، النزول الأبيض)
٦.	أمراض القدم والجلد—اذكر بالتفصيل (البتر، القرحة)
٧.	حالات غيرها—اذكرها بالتفصيل
٨.	ارتفاع مستوى الدهون بالدم
٩.	لا شيء

## ٥- يرجى ذكر جميع الأدوية التي تتناولها مع جرعاتها

اسم الدواء	الجرعة

## ٦- يرجى ذكر جميع المقاسات المطلوبة في هذه الزيارة كما هو موضح أدناه:

القياس خلال ٣ أشهر	
الوزن (كغم)	
الطول (سم)	
مؤشر كتلة الجسم (كغم/متر <sup>٢</sup> )	
HbA1C	

٤.	هل يشمل عملك ممارسة نشاط بدني معتدل بما يتسبب بارتفاع ملحوظ في معدل التنفس ونبضات القلب مثل المشي السريع [أو حمل أشياء خفيفة] لفترة ١٠ دقائق متصلة على الأقل؟	١- نعم ٢- لا	إن كانت الإجابة لا فانتقل إلى السؤال ٨
٥.	في خلال أسبوع اعتيادي، كم مرة تمارس نشاطا بدنيا معتدلا كجزء من عملك؟	عدد الأيام	لا
٦.	كم الوقت الذي تقضيه وأنت تمارس النشاط البدني المعتدل في العمل خلال يوم واحد	الدقائق: الساعات	لا : لا دقائق ساعات
٧.	كم من الوقت تقضيه في العمل/وأنت تعمل في يوم اعتيادي واحد	الدقائق: الساعات	لا : لا دقائق ساعات
<b>التنقل من وإلى مختلف الأماكن (يشمل التنقل من وإلى العمل)</b>			
الأسئلة التالية تستثني النشاط البدني المذكور سابقا في موقع العمل، الآن أريد أن أسألك عن الطريقة المعتادة للتنقل من وإلى الأماكن المختلفة مثل العمل والتسوق وشراء الحاجيات ودور العبادة.			
٨.	هل تمشي أو تستعمل الدراجة الهوائية لفترة ١٠ دقائق متواصلة على الأقل للوصول إلى حيث تريد؟	١- نعم ٢- لا	إن كانت الإجابة لا فانتقل إلى السؤال ١١
٩.	خلال الأسبوع الاعتيادي، في كم يوم تمشي أو تستخدم الدراجة الهوائية لفترة ١٠ دقائق متواصلة على الأقل؟	عدد الأيام	لا
١٠.	كم من الوقت تقضيه وأنت تمشي أو تستعمل الدراجة الهوائية للتنقل خلال اليوم الاعتيادي؟	الدقائق: الساعات	لا : لا دقائق ساعات
<b>الأنشطة الترفيهية</b>			
الأسئلة التالية تستثني ما ذكر في أعلاه عن العمل والتنقل من مكان لآخر، الآن أريد أن أسألك عن الرياضات والأنشطة التي تمارسها لتحافظ على رشافتك ولتستمتع بوقتك.			
١١.	هل تمارس أي رياضة أو نشاط ترفيهي يتطلب بذل مجهود بدني شديد ويتسبب في ارتفاع كبير في معدل التنفس ونبضات القلب مثل الركض وكرة القدم لفترة ١٠ دقائق متصلة على الأقل؟	١- نعم ٢- لا	إن كان الجواب لا فانتقل إلى السؤال ١٤
١٢.	خلال الأسبوع الاعتيادي، في كم يوم تمارس أي رياضة أو نشاط ترفيهي يتطلب بذل مجهود بدني شديد؟	عدد الأيام	لا
١٣.	كم من الوقت تقضيه في ممارسة رياضة أو نشاط ترفيهي يتطلب بذل مجهود بدني شديد خلال اليوم الاعتيادي؟	الدقائق: الساعات	لا : لا دقائق ساعات
١٤.	هل تمارس أي رياضة أو نشاط ترفيهي يتطلب بذل مجهود بدني معتدل ويتسبب في ارتفاع ملحوظ في معدل التنفس ونبضات القلب القدم لفترة ١٠ دقائق متصلة على الأقل؟	٣- نعم ٤- لا	إن كان الجواب لا فانتقل إلى السؤال ١٧

١٥.	خلال الأسبوع الاعتيادي، في كم يوم تمارس أي رياضة أو نشاط ترفيهي يتطلب بذل مجهود بدني معتدل ؟	عدد الأيام
١٦.	كم من الوقت تقضيه في ممارسة رياضة أو نشاط ترفيهي يتطلب بذل مجهود بدني معتدل خلال اليوم الاعتيادي؟	الدقائق: الساعات دقائق ساعات
<b>وقت الجلوس</b> <b>الأسئلة التالية هي عن الجلوس أو التمدد في العمل والمنزل وأثناء التنقلات ومع الأصدقاء ويشمل الأوقات التي تقضيها جالسا على المكتب ومع الأصدقاء وأثناء الجلوس بالسيارة أو الباص أو القطار أو أثناء القراءة ولعب الورق ومشاهدة التلفاز ولكن لا يشمل الوقت المصروف بالنوم</b>		
١٧.	كم من الوقت تصرفه عادة أثناء الجلوس أو التمدد في خلال يوم اعتيادي واحد؟	الدقائق: الساعات دقائق ساعات
١٨.	كم من الوقت تقضيه عادة أثناء الجلوس أو التمدد بالعمل؟	الدقائق: الساعات دقائق ساعات
١٩.	كم من الوقت تقضيه عادة بالجلوس أو التمدد عادة أثناء السفر؟	الدقائق: الساعات دقائق ساعات
٢٠.	كم من الوقت تقضيه عادة بالجلوس في وقت الترفيه والتسلية (مثلا بالبيت لمشاهدة التلفاز أو جلسات السمر مع الأصدقاء لتناول القهوة أو الخياطة أو العمل بالبيت؟)	الدقائق: الساعات دقائق ساعات

الوقت:



## Appendix 7.4: The “MOVEdiabetes” general wellbeing questionnaire

<p>Q1 In general, would you say your health is?</p>  <p>Excellent <input type="checkbox"/>      Very good <input type="checkbox"/>      Good <input type="checkbox"/>      Fair <input type="checkbox"/>      Poor <input type="checkbox"/></p>
<p>Q2 In general, would you say your sleep is?</p>  <p>Excellent <input type="checkbox"/>      Very good <input type="checkbox"/>      Good <input type="checkbox"/>      Fair <input type="checkbox"/>      Poor <input type="checkbox"/></p>
<p>Q3 Does your health now limit you in the kinds or amounts of moderate activities you can do, like moving a table, carrying groceries, or bowling?</p>  <p>Yes, limited a lot <input type="checkbox"/>      Yes, limited a little <input type="checkbox"/>      No, not limited at all <input type="checkbox"/></p>
<p>Q4 Does your health now limit you in the kinds or amounts of vigorous activities you can do, like lifting heavy objects, running or participating in strenuous sports?</p>  <p>Yes, limited a lot <input type="checkbox"/>      Yes, limited a little <input type="checkbox"/>      No, not limited at all <input type="checkbox"/></p>
<p>Q5 How much of the time have you Accomplished less in certain kinds or amounts of work, or housework, because of your <u>PHYSICAL HEALTH</u>?</p>  <p>All of the time <input type="checkbox"/>    Most of the time <input type="checkbox"/>      Some of the time <input type="checkbox"/>      A little of the time <input type="checkbox"/>  None of the time <input type="checkbox"/></p>
<p>Q6 How much of the time you had limitations in the kind of work or other activities as a result of your <u>PHYSICAL HEALTH</u>?</p>  <p>All of the time <input type="checkbox"/>    Most of the time <input type="checkbox"/>      Some of the time <input type="checkbox"/>      A little of the time <input type="checkbox"/>  None of the time <input type="checkbox"/></p>
<p>Q7 How much of the time have you Accomplished less in certain kinds or amounts of work, or housework, because of your <u>EMOTIONAL PROBLEMS</u> (such as feeling depressed or anxious)?</p>  

All of the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> A little of the time <input type="checkbox"/> None of the time <input type="checkbox"/>
Q8 How much of the time you had limitations in the kind of work or other activities as a result of <u>any EMOTIONAL PROBLEMS</u> (such as feeling depressed or anxious)?   All of the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> A little of the time <input type="checkbox"/> None of the time <input type="checkbox"/>
Q9 How much bodily pain have you had during the past 4 weeks?   Not at all <input type="checkbox"/> A little bit <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit <input type="checkbox"/> Extremely <input type="checkbox"/>
Q10 Have you felt calm and peaceful during the last 4 weeks?   All of the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> A little of the time <input type="checkbox"/> None of the time <input type="checkbox"/>
Q11 Did you have a lot of energy during the past 4 weeks?   All of the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> A little of the time <input type="checkbox"/> None of the time <input type="checkbox"/>
Q12 Have you felt downhearted and depressed during the past 4 weeks?   All of the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> A little of the time <input type="checkbox"/> None of the time <input type="checkbox"/>
Q13 How much of the time has your <u>PHYSICAL HEALTH OR EMOTIONAL PROBLEMS</u> interfered with your social activities (like visiting friends, relatives)?   All of the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> A little of the time <input type="checkbox"/> None of the time <input type="checkbox"/>

## Appendix 7.5: The “MOVEdiabetes” consultation workbook

### Section 1- Practice being clear about the current messages and



“MOVEdiabetes”

Physical activity consultation workbook

meanings around physical activity

#### 1) Discuss what physical activity is and what moderate and vigorous intensity means

Explain different forms of physical activity

- Active living (Walking, taking the stairs)
- Exercise (Swimming, exercise class)
- Sport (Football, hockey)

Explain intensity in simple terms- the ‘talk test’

#### 2) Assessing ‘stage of change’ practice using the definitions below to determine how ready the client is to change

Regular Physical Activity

- Accumulating at least 30 minutes of moderate intensity physical activity 5 days of the week or 150 minutes of moderate in total each week
- Participating in 75 minutes of vigorous exercise a week
- A combination of these that equates to 150 minutes of moderate each week

1: Not thinking about achieving regular physical activity

2: Starting to think about doing more physical activity

3: Being physically active occasionally and would like to become more active

4: Being regularly physically active for less than 6 months

5: Being regularly physically active for longer than 6 months

**Section two – practice understanding the person’s reasons for being active and help them see benefits they might feel from taking part in more activity. Investigate their pros and cons for being more active and explore with them how it might be possible to overcome some of the barriers noted**

### **3) Why be more active?**

Ask about their reasons for coming today

Discuss benefits of physical activity for individual

### **4) Decision balance**

Go through pros & cons of increasing physical activity

Pros and cons of becoming more active

Your pro's of becoming more active	Your con's of becoming more active
------------------------------------	------------------------------------


### 5) Overcoming barriers

Discuss ways of overcoming barriers to becoming more active

Your con's of becoming more active	Ways to overcome con's

**Section three: Practice setting goals for the short and longer term to help clients get a clear plan that they can try. Help them set initial goals that they can do and gain success from.**

**6) Identifying opportunities and setting goals**

Can they think of ways to increase their activity?

Activities you might consider

Planning what to do and where and when it will take place. Make first week goals within reach from where they are now. Two to three days with new activities is a good way to start. Think of taking at least 4 weeks to build up to the 30 minutes on most days of the week target.

Day of Week	What When and Where	✓ when you achieve
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Develop longer term goals

1 month	3 months	6 months
Walk back from work (10 minutes) at least 3 days a week	Increase walking to accumulate at least 40 minutes a day, 5 times a week	Complete sponsored 4km walk


\* Remember SMARTER

Thank the client and provide encouragement for continuing activity.



### Appendix 8.1: The “MOVEdiabetes” self-efficacy scale

How confident are you that you can engage in physical activity when you.....			
	No Confidence	Complete Confidence	N/A
Are tired?	1 2 3 4 5 6 7 8 9 10		
Are in a bad mood?	1 2 3 4 5 6 7 8 9 10		
Feel you don't have the time?	1 2 3 4 5 6 7 8 9 10		
During bad weather	1 2 3 4 5 6 7 8 9 10		
When you don't have access to PA resources	1 2 3 4 5 6 7 8 9 10		

These next questions are about physical activity itself; that is, engaging in the activity of your choice, assuming you were able to get to the place to exercise and that you have all the necessary equipment. How confident are you that you can do the following?

	No Confidence	Complete Confidence	N/A

Follow directions from an Instructor (if applicable)?	1 2 3 4 5 6 7 8 9 10	
Pace yourself during the activity to avoid overexertion?	1 2 3 4 5 6 7 8 9 10	
Perform the required movements when you feel any physical discomfort?	1 2 3 4 5 6 7 8 9 10	
Check how hard the activity is making you work?	1 2 3 4 5 6 7 8 9 10	

The next questions are about scheduling time for exercise. How confident are you that you can do the following?			
	No Confidence	Complete Confidence	N/A
Arrange your schedule to perform PA regularly no matter what.	1 2 3 4 5 6 7 8 9 10		
Overcome lack of social support that could be an obstacle to performing PA	1 2 3 4 5 6 7 8 9 10		
Make up times when you missed your regular PA session.	1 2 3 4 5 6 7 8 9 10		

## Appendix 8.2: The “MOVEdiabetes” social support scale

Below is a list of things people might do or say to someone who is trying to exercise regularly including walking . If you are not trying to exercise, then some of the questions may not apply to you, but please read and give an answer to every question. Please rate each question twice. Under family, rate how often anyone living in your household has said or done what is described during the last three months. Under friends, rate how often your friends, acquaintances, or co-workers have said or done what is described during the last three months.

Please write one number from the following rating scale in each space:1-5

	During the past three months, my family (or members of my household) or friends:	Family	Friends
1	Exercised with me (or if you are a female), asked someone to accompany me.		
2	Offered to exercise with me or offered to drive me to the nearest PA facility		
3	Gave me helpful reminders to exercise ("Are you going to exercise tonight?").		
4	Gave me encouragement. To stick with my exercise program.		
5	Changed their schedule so we could exercise together.		
6	Discussed exercise with me.		
7	Complained about the time I spend exercising.		
8	Criticized me or made fun of me for exercising.		
9	Gave me rewards for exercising (bought me something or gave me something I like).		
10	Planned for exercise on recreational outings.		
11	Helped plan activities around my exercise.		
12	Asked me for ideas on how they can get more exercise including to select appropriate PA clothing.		
13	Talked about how much they like to exercise.		

### Appendix 8.3: Results from factor analysis of the self-efficacy scale

The principal component analysis was utilised followed by Oblimin rotation. At baseline and 12 months, the Kaiser–Meyer–Oklin (KMO) measure of sampling adequacy was 0.64 & 0.77, which were in consistency with Bartlett’s Test of Sphericity (approximate chi-square = 1420.1 & 1251.9,  $P < 0.001$ ), indicating sufficient sampling and sufficient correlation.

Except for item/question Q9 at baseline, all the other 11 items/questions of scale were retained in the factor analysis as each had a factor loading of more than 0.3. Table 2 shows proportion of item’s variance explained by the extracted factors loadings at baseline and 12 months. This indicates that each item shared some common variance with other items. Given these overall indicators, factor analysis was regarded to be suitable with all the 12 items/questions (Table 1).

**Table 1: Factor loadings from the exploratory factor analysis applied on self-efficacy sum scores at baseline and 12 months**

Items/questions	Factor loadings at baseline	Factor loadings at 12 months
Q1 How confident are you that you can engage in physical activity when you are tired?	0.5	0.4
Q2 How confident are you that you can engage in physical activity when you are in a bad mood?	0.8	0.5
Q3 How confident are you that you can engage in physical activity when you feel you don’t have time?	0.7	0.4
Q4 How confident are you that you can engage in physical activity during bad weather?	0.8	0.6
Q5 How confident are you that you can engage in physical activity when you don’t have access to PA facility?	0.4	0.5

Q6 How confident are you that you can follow PA directions from an instructor?	0.6	0.7
Q7 How confident are you that you can pace yourself during the activity to avoid overexertion?	0.3	0.8
Q8 How confident are you that you can perform the required movements when you feel discomfort?	0.5	0.8
Q9 How confident are you to check how hard the activity is making you work?	0.5	0.3
Q10 How confident are you to arrange your schedule to perform PA regularly no matter what?	0.8	0.6
Q11 How confident are you that you can overcome lack of social support as an obstacle to performing PA?	0.3	0.5
Q12 How confident are you that you can make up time when you missed your regular PA session	0.8	0.7

However, the scree plot showed three meaningful factors with an eigenvalue of  $>1.5$  at both baseline and 12 months which is consistent with the categorisation within the “MOVEdiabetes” self-efficacy scale. Table 2 shows the contribution of the three factors in explaining the variance in the study data at baseline and 12 months.

**Table 2: Factors extracted from the principal component analysis for self-efficacy sum scores at baseline and 12 months**

Total variance explained	At baseline	At 12 months
Factor 1	25.9	37.9
Factor 2	16.3	12.8
Factor 3	15.7	10.0

Furthermore, after performing Oblimin rotation, table 3 shows how the items/questions contributed to the variance of the loaded 3 factors (a value of

>0.4 represented higher contribution). Cross loading of items/questions within data from the scale scores were identified too. The factor correlation matrix showed that the Items that could be considered cross-loaded with correlation of >0.3-0.4, which means that these items are considered complex items whereas all other items were simple items.

**Table 3: items/questions loadings on the identified factors on self-efficacy sum scores at baseline and 12 months**

At baseline	At 12 months						
Items/ questions	1	2	3	Items/ questions	1	2	3
Q4	0.9*			Q8	0.3	0.8*	
Q2	0.9*			Q12	0.8*		0.3
Q3	0.8*			Q11	0.6*		0.5*
Q12			0.9*	Q3	0.3		0.6*
Q10			0.9*	Q9	0.2	0.5*	0.2
Q7		0.5*		Q2	0.7*		
Q9				Q5	0.6*	0.3	
Q6		0.7*		Q7	0.4	0.9*	
Q8		0.7*		Q6	0.3	0.7*	
Q1	0.2		0.5*	Q4	0.7*		0.2
Q5	0.3		0.5*	Q10	0.4		0.7*
Q11	-0.3		0.4	Q1	0.5*	0.3	0.2

\* High item/question contribution

The inter-item correlations were also evaluated, which ranged from -0.1 to 0.9 at baseline and -0.2 to 0.8 at 12 months. The highest inter-item correlation at

baseline was noted among Items/question 2 and 3 ( $r=0.7$ ) and 2 and 4 ( $r=0.9$ ). Similarly, high inter-item correlation at 12 months was noted between Item 6 and 7 ( $r=0.8$ ) and Item 7 and 10 ( $r=0.8$ ).

## Appendix 8.4: Results from factor analysis of the social support (family) scale

Exploratory factor analysis showed KMO value of 0.50 & 0.52 at baseline and 12 months respectively (chi-square = 237.1 & 346.5,  $P < 0.001$ ), indicating sufficient sampling and sufficient correlation.

Except for item/question Q7 at baseline, and Q1 at 12 months, all the other items/questions of scale were retained in the factor analysis as each had a factor loading of more than 0.3. Table 1 shows proportion of item's variance explained by the extracted factors loadings at baseline and 12 months. This indicates that each item shared some common variance with other items. Given these overall indicators, factor analysis was regarded to be potentially suitable with all the 13 items/questions of the family social support scale (Table1).

**Table 1: Factor loadings from the exploratory factor analysis on social support sum scores from family at baseline and 12 months**

Items/questions	Factor loadings at baseline	Factor loadings at 12 months
Q1 Exercised with me	0.6	0.3
Q2 Offered to exercise with me.	0.5	0.6
Q3 Gave me helpful reminders to exercise	0.7	0.7
Q4 Gave me encouragement to stick with my exercise program.	0.7	0.7
Q5 Changed their schedule so we could exercise together	0.7	0.6
Q6 Discussed exercise with me.	0.7	0.6
Q7 Complained about the time I spend exercising.	0.3	0.6
Q8 Criticized me or made fun of me for exercising.	0.6	0.7
Q9 Gave me rewards for exercising	0.5	0.5



Q10 Planned for exercise on recreational outings	0.6	0.7
Q11 Helped plan activities around my exercise	0.5	0.7
Q12 Asked me for ideas on how they can get more exercise	0.5	0.7
Q13 Talked about how much they like to exercise.	0.6	0.7

PCA identified six factors with eigenvalue of  $>1.0$  which were consistent with the categorisation within the social support scale. Table 2 shows the contribution of the 6 factors in explaining the variance in the study data at baseline and 12 months.

**Table 2: Factors extracted from the principal component analysis for sum scores on social support from family at baseline and 12 months**

Total variance explained (%)	At baseline	At 12 months
Factor 1	14.3	15.2
Factor 2	11.1	12.7
Factor 3	10.8	11.1
Factor 4	10.2	9.6
Factor 5	8.8	8.9
Factor 6	7.8	8.3

Furthermore, after performing Oblimin rotation, cross loading of items/questions in the scale were identified. Overall; the contribution of the item/questions across the identified 6 factors varied over 12 months Table 3. The factors correlation matrix showed that the Items that could be considered cross-loaded with correlation of 0.3 to 0.4.

**Table 3: Items/questions loadings on the identified factors from social support sum scores (Family) at baseline and 12 months**

	At baseline						At 12 months						
Items/ questions	1	2	3	4	5	6	Items/ questions	1	2	3	4	5	6
Q13	0.6*		0.3			-0.2	Q8	0.8*					
Q3	0.6*	-0.3	-0.3	0.2			Q9	0.8*	0.2				
Q12	0.5*			-0.2	-0.4	0.2	Q5		0.7*	0.2	0.2		
Q10	0.4	0.2	0.3		-0.4	0.3	Q10	0.2	0.6*				
Q8	0.2	0.6*	-0.4				Q11	-0.3	0.5*	-0.4			
Q7		0.3	0.2	0.3			Q13			-0.7*			
Q11		-0.3	0.5*	-0.3			Q2			-0.6*	-0.2		0.4
Q2		0	.2	0.5*	0.2	-0.2	Q12				0.8*		-0.2
Q9	-0.2	0.3		0.6			Q4				0.7*		0.3

Q5	0.4	-0.2	-0.3	0.4	0.3		Q6					0.7*	
Q6	0.2	0.3		-0.4	0.4	0.2	Q7	0.2				0.7*	
Q4			0.2		0.5*	0.6*	Q1		-0.3			0.3	0.2
Q1	0.4	0.3		-0.3	0.2	-0.4	Q3						0.8*
Q13	0.6*		0.3			-0.2	Q8	0.8*					

\* High Item/question contribution

The inter-item correlations were also evaluated, which ranged from -0.1 to 0.4 at baseline and -0.2 to 0.8 at 12 months. No high interactions (above 0.70) were identified indicating null item redundancy.

## Appendix 8.5: Results from factor analysis of the social support (friends) scale

KMO measure of sampling adequacy was poor, but significant (0.49 & 0.54 at baseline and 12 months respectively (chi-square = 266.9 & 369.7,  $P < 0.001$ ), indicating sufficient sampling and sufficient correlation.

Except for item/question Q3 & 4 at 12 months, all the other items/questions of scale were retained in the factor analysis as each had a factor loading of more than 0.3. Table 1 shows proportion of item's variance explained by the extracted factors loadings at baseline and 12 months. This indicates that each item shared some common variance with other items. Given these overall indicators, factor analysis was regarded to be potentially suitable with all the 13 items/questions of the friend social support scale.

**Table 1: Factor loadings from the exploratory factor analysis on social support sum scores from friends**

Items/questions	Factor loadings at baseline	Factor loadings at 12 months
Q1 Exercised with me	0.9	0.6
Q2 Offered to exercise with me.	0.6	0.7
Q3 Gave me helpful reminders to exercise	0.6	0.3
Q4 Gave me encouragement to stick with my exercise program	0.7	0.4
Q5 Changed their schedule so we could exercise together	0.5	0.7
Q6 Discussed exercise with me.	0.7	0.6
Q7 Complained about the time I spend exercising.	0.8	0.7
Q8 Criticized me or made fun of me for exercising.	0.7	0.5

Q9 Gave me rewards for exercising	0.7	0.6
Q10 Planned for exercise on recreational outings	0.7	0.6
Q11 Helped plan activities around my exercise	0.6	0.5
Q12 Asked me for ideas on how they can get more exercise	0.6	0.6
Q13 Talked about how much they like to exercise.	0.6	0.5

PCA identified seven and five factors with an eigenvalue of  $>1.0$  which is inconsistent with the categorisation proposed by Sallis et al. (1987) within the social support scale. Table 2 shows the contribution of the extracted factors in explaining the variance in the study data at baseline and 12 months.

**Table 2: Factors extracted from the principal component analysis at baseline and 12 months (social support from friends)**

Total variance explained (%)	At baseline	At 12 months
Factor 1	13.4	16.2
Factor 2	12.1	13.5
Factor 3	11.2	11.171
Factor 4	9.6	8.9
Factor 5	8.7	8.2
Factor 6	8.2	-
Factor 7	8.0	-

Furthermore, after performing Oblimin rotation, cross loading of items/questions in the scale were identified Table 3. Overall, the contribution of items/questions over the loaded factors was different at both baseline and 12 months.

**Table 3: Items/questions loadings on the identified factors from social support sum scores (Friends) at baseline and 12 months**

Baseline								12 months					
Items/ questions	1	2	3	4	5	6	7	Items/ questions	1	2	3	4	5
Q8	0.7*	0.4	0.2					Q2	0.9*				
Q9	0.6*	0.3	0.4		0.2			Q1	0.8*				-0.2
Q11		0.7*		0.2				Q3	0.5*				
Q10		0.	0.4	0.2			0.4	Q9		0.8*			
Q13			0.6*	0.4				Q10		0.7*	0.2		
Q3	0.4		0.5*	0.2	0.3		0.3	Q11		0.5*		-0.4	
Q2		0.5		0.5*	0.4			Q13		0.3	0.6*		
Q1				0.5*	0.7*			Q4			-0.5*		

Q4	0.5*	0.2	0.3		0.5		0.2	Q8	0.2	0.4	0.5*		
Q6	0.			0.3		0.7*		Q7			0.2	0.8*	
Q7		0.3		0.5*		0.4	0.4	Q12			0.4	-0.6	
Q5	0.4	0.2		0.2		-0.4	0.2	Q5					0.7*
Q12	0.3	0.2	0.4				0.5	Q6					0.7*

\* High item/question contribution



The inter-item correlations ranged from -0.01 to 0.5 at baseline and -0.08 to 0.6 at 12 months. No high interactions (above 0.7) were identified indicating null item redundancy.

## Appendix 9.1: The “MOVEdiabetes” participants’ exit survey



### “MOVEdiabetes” End of Study Questionnaire Participant

Thank you for participating in the “MOVEdiabetes” study over the past 12 months. Please take a few minutes to complete this evaluation questionnaire **by placing a tick in the relevant box and answering questions as required**—your replies may help us improve physical activity services in routine diabetes care

Please note:

- Your answers are being assessed independently.
- Your answers will be kept anonymous and confidential.

1. Overall, how satisfied were you with the “MOVEdiabetes” project?

Very dissatisfied	Quite dissatisfied	Neither satisfied nor dissatisfied	Quite satisfied	Very satisfied

2. Do you feel you received enough information about the project at the start?

Far too little	Not enough information	Sufficient information	More information than was necessary	Far too much information

3. Which aspects of the project do you wish you'd had more information on?


4. Did you have enough opportunity to ask questions during the project?

Not at all	Rarely	Every once in a while	Sometimes	Very often

5. Were your questions answered to your satisfaction?

Not at all	Rarely	Every once in a while	Sometimes	Yes, completely

6. Which of the following most closely describes the number of face-to-face consultations you received?

No visits	1 visits	2 visits	3 visit	More than 3

7. How likely are you to recommend "MOVEdiabetes" to other people?

Very unlikely	Quite unlikely	Neither likely nor unlikely	Quite likely	Very likely

8. How did you find coming up to the health centre for your appointments?

Very difficult	Quite difficult	Neither easy nor difficult	Quite easy	Very easy

9. Having taken part, do you think this program is appropriate in diabetes care?

No, not at all appropriate	Quite inappropriate	Neither appropriate or inappropriate	Quite appropriate	Very appropriate

10. was your physical activity behaviour change acceptable?

Not at all acceptable	Not very acceptable	Neither acceptable or unacceptable	Quite acceptable	Very acceptable To a

11. What were the challenges of taking part in this project?

--

12. What were the barriers to increasing your physical activity behaviour?

--

13. Please rate the consultations you received

	Very poor	poor	acceptable	good	Very good
Content					
Relevance					
Duration per consultation					
Frequency					

14. Please rate using pedometers

	Very poor	Poor	Neither poor nor good	Fairly good	Very good
Length of device use					
Importance to diabetes management					
Wearing it (put it on and off)					
Usefulness					

15. Please rate the WhatsApp communication you received

	Very poor	Poor	Neither poor nor good	Fairly good	Very good
Content					
Relevance					
Time required					


Frequency of messages					
Supportiveness					

16. Gender	
Male	Female

17. Please feel free to make any other general comments in the space below:

Thank you for your participation in the "MOVEdiabetes" study and for completing this survey.

## Appendix 9.2: The “MOVEdiabetes” project officers’ exit survey

	<h3>“MOVEdiabetes” End of Study Questionnaire Project officer</h3>
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Thank you for participating in the “MOVEdiabetes” study over the past 12 months. Please take a few minutes to complete this evaluation questionnaire **by placing a tick in the relevant box and answering questions as required** –your replies may help us improve physical activity services in routine diabetes care

Please note:

- Your answers are being assessed independently.
- Your answers will be kept anonymous and confidential.

1. Overall, how satisfied were you with the “MOVEdiabetes” project?				
Very dissatisfied	Quite dissatisfied	Neither satisfied nor dissatisfied	Quite satisfied	Very satisfied

2. Do you feel you received enough training about the project at the start?				
Far too little	Not enough information	Sufficient information	More information than was necessary	Far too much information

3. Which aspects of the project do you wish you’d had more information on?				

4. Did you have enough opportunity to ask questions during the project?				
Not at all	Rarely	Every once in a while	Sometimes	Very often

5. Were your questions answered to your satisfaction?				
Not at all	Rarely	Every once in a while	Sometimes	Yes, completely

6. Which of the following most closely describes the number of face-to-face consultations you conducted?

No visits	1 visits	2 visits	3 visit	More than 3

7. Having taken part, do you think this programme is appropriate in diabetes care?

No, not at all appropriate	Quite inappropriate	Not sure	Quite appropriate	Very appropriate

8. What were the challenges of taking part in this project?

--

9. Please rate the consultations you conducted

	Very poor	Poor	Acceptable	Good	Very good
Content					
Relevance					
frequency					

10. Please rate the use of pedometers as physical activity self-monitoring tool

	Very poor	Poor	Acceptable	Fairly good	Very good
Usefulness					
Relevance to diabetes management					

11. Please rate the WhatsApp communication you were involved in					
	Very poor	Poor	Acceptable	Fairly good	Very good
Content					
Relevance					
Time required					
Frequency of messages					

12. How suitable is this project to the current diabetes primary care?					
	Not at all suitable	Not very suitable	Not sure	Quite suitable	Very suitable
Consultations					
Pedometers					
Personal PA diaries					
WhatsApp					

13. Gender	
Male	Female


14. Are you (1-dietician, 2- doctor, 3- nurse, 4-health educator, 5-other (specify))

15. Please feel free to make any other general comments in the space below:

Thank you for your participation in the "MOVEdiabetes" study and for completing this survey.



### Appendix 9.3: The “MOVEdiabetes” observatory intervention check list

		<b>“MOVEdiabetes”</b> <b>Observer checklist on intervention</b> <b>delivery</b>		
COMPONENTS USED	Not done 1	Partially done 2	Completely done 3	Description
1. Set the scene				Introductions, overview of consultation, reasons for attending
2. Assessed stage of change				Assessed stages of change for PA
3. PA guidelines discussed				Explained current activity guidelines
4. Assessed current activity status				Explained light, moderate and vigorous intensity activity and the different modes of activity.
5. Discussed past and present activities				Discover client's likes and dislikes of activities they have done recently and in the past
6. Assessed PA & sitting time				Assessed PA and sitting time via GPAQ
7. Completed decisional balance				Encouraged client to explore pros and cons of change with discussion on overcoming cons. If appropriate, consultant provided information on benefits of PA. Client elicited own pros and cons for change and ways to overcome cons.
8. Identified & addressed barriers to change				Client identified own barriers and elicited ways to overcome cons.
9. Discrepancy between current activity status & guidelines				Explanation of current activity guidelines.
10. Identified opportunities for activity				Took into account client's likes and dislikes of past and present activities, barriers to activity, current lifestyle and needs.
11. Assessed and developed self-efficacy				Assess confidence to overcome barriers to engaging in PA, follow PA instructions and maintain regular PA.
12. Set Goals				SMART goals set by client with guidance by consultant.
13. Established support				Helped client to identify what support they need from family/friends.

14. Relapse prevention				Encouraged client to develop ways to avoid high risk situations or deal with them.
15. Ensure pedometer use				Reviewed pedometer if working and replace if damaged.
16. Ensure use of WhatsApp				Reviewed WhatsApp if activated and all messages are well received.
17. Accelerometer findings discussed				Explained accelerometers' findings on sitting time, standing and step counts.
18. Reviewed weekly step counts				Reviewed weekly diaries if completed
19. Asked adverse reactions				Recorded any adverse reaction related to engaging in the project
20. Next appointment discussed				Discussed next appointment

Other comments:

### Appendix 9.4: Quotations from the participant (open questions exit survey):

Themes	Responses (quotes)	Participants' health centre	Number of participants (%)
Q1: Aspects of the project where more information was needed			
No response			47 (56.1)
Types of exercises in diabetes	<p>What type of exercise is suitable for patients with diabetes?</p> <p>Can patients with diabetes do aerobic exercises?</p> <p>What about resistance exercises in diabetes management?</p> <p>Is walking sufficient to control diabetes?</p> <p>What exercises we can do?</p> <p>What is the best exercise for patients with diabetes?</p> <p>Is running good for patients with diabetes?</p> <p>How can I exercise if my sugar is high?</p> <p>Is walking an enough exercise?</p> <p>What about playing football, is it enough one a week?</p> <p>What can I do to increase my physical activity?</p> <p>What about swimming?</p> <p>I like to go to the gym, but not sure of the physical activity machines to use?</p>	<p>HC1</p> <p>HC3</p> <p>HC2</p> <p>HC2</p> <p>HC4</p> <p>HC1</p> <p>HC1</p> <p>HC1</p> <p>HC4</p> <p>HC3</p> <p>HC3</p> <p>HC1</p> <p>HC1</p> <p>HC3</p> <p>HC3</p> <p>HC1</p> <p>HC3</p>	18 (22)

	<p>Can I walk on the beach?</p> <p>Is playing basketball a good exercise?</p> <p>What exercise is suitable at workplace?</p> <p>How to exercise in hot weather?</p> <p>For busy house wife like me, what can I do to increase my physical activity?</p>	<p>HC2</p> <p>HC1</p>	
Use of accelerometers	<p>Can we attach the accelerometers on the arm?</p> <p>What is the purpose of the accelerometers?</p> <p>I don't like the skin irritation from accelerometers, can I remove it?</p> <p>Can we use them while swimming?</p> <p>Does it carry any side effects?</p> <p>Why put the accelerometers on upper thigh?</p> <p>Why it is used in this study?</p> <p>Why some patients are wearing them and some are not?</p> <p>Can we keep them by ourselves?</p> <p>Can we travel with these on?</p> <p>Can we pray with these on?</p>	<p>HC3</p> <p>HC1</p> <p>HC1</p> <p>HC1</p> <p>HC4</p> <p>HC3</p> <p>HC1</p> <p>HC1</p> <p>HC3</p> <p>HC2</p> <p>HC2</p>	11 (13.4)
PA options in presence of comorbidities	<p>What can I do if I have joint pain?</p> <p>What is the best physical activity in case of high blood pressure?</p> <p>I have glaucoma, can I exercise?</p> <p>How can I exercise with back pain?</p>	<p>HC2</p> <p>HC3</p> <p>HC2</p> <p>HC1</p> <p>HC3</p>	6 (8.5)

	<p>I have muscular pain when I perform any physical activity, what can I do?</p> <p>What is PA recommendations for patients with diabetes on insulin?</p>	HC1	
Q2: Challenges of taking part in this project			
No response			61 (74.4)
Nature of PA measurment tools	<p>The questionnaires are too long and time consuming</p> <p>The device attached on my thigh is not comfortable</p> <p>I get confused sometimes if you give me too much instructions</p> <p>Accelerometers are not comfortable</p> <p>Difficult to respond to the long questionnaires</p> <p>Long and difficult questionnaires</p> <p>I don't understand all the questions in the questionnaires</p> <p>I cannot wear accelerometer during sleeping time</p> <p>Questions on PA are difficult</p> <p>Too much instructions</p> <p>Difficult to follow all PA guidelines</p> <p>Too many papers in the questionnaire</p> <p>Consultations are long due to exhausting questionnaires</p>	<p>HC4</p> <p>HC1</p> <p>HC3</p> <p>HC3</p> <p>HC2</p> <p>HC1</p> <p>HC2</p> <p>HC1</p> <p>HC4</p> <p>HC2</p> <p>HC1</p> <p>HC2</p> <p>HC1</p>	13 (15.9)

Time limitation	<p>I don't have time to attend the PA consultations</p> <p>Time is not enough for my diabetes care and PA advice</p> <p>I am short of time</p> <p>Time is short</p> <p>Time is not enough</p> <p>Difficult to add PA in diabetes care, too busy and no time</p> <p>All staff are busy. They have no time for PA</p> <p>Diabetes clinics are too busy</p>	HC2	8 (9.8)
Q3: Barriers to increasing physical activity behaviour other			
No response			46(56.1)
Weather	<p>It is too hot outside, I can't walk</p> <p>What can we do in summer times</p> <p>Oman is very hot in the summer</p> <p>I can't walk if it's too hot</p> <p>What can I do if the weather is too hot</p> <p>Sometimes I try to walk outside, but I can't due to extreme heat</p> <p>I don't like walking in the summer</p> <p>The weather is not friendly</p> <p>It is inconvenient to do PA in hot weather</p> <p>The weather is not suitable</p> <p>We need to think of alternative in door physical activities if its hot outside</p>	<p>HC4</p> <p>HC3</p> <p>HC1</p> <p>HC4</p> <p>HC3</p> <p>HC4</p> <p>HC1</p> <p>HC1</p> <p>HC1</p> <p>HC4</p> <p>HC4</p> <p>HC4</p>	16(19.5)

	<p>If its hot outside, it's better to avoid walking especially when comorbidities exist</p> <p>It's hot throughout the year</p> <p>There is no way to avoid walking in the summer but one should take care</p> <p>How can I play football if the weather is bad</p> <p>What can I do if it's hot outside?</p>	<p>HC3</p> <p>HC2</p> <p>HC2</p> <p>HC4</p>	
Lack of time	<p>I have no time for physical activity</p> <p>Time is not enough</p> <p>I work for a long time and become tired at the end of the day</p> <p>We are too busy</p> <p>I can't make time for physical activity</p> <p>I am busy with kids all the time</p> <p>I work two shifts most days of the week</p> <p>I am too tired to do any physical activity due to lack of time</p> <p>I have many work responsibilities that prevents me from performing PA</p> <p>Time is not enough especially in weekends</p> <p>I have to make time for physical activity</p> <p>Time is short</p> <p>Time management is difficult for physical activity</p> <p>I am busy with kids at home I have no time for physical activity</p> <p>Most of the times I am busy with work, family and friends</p>	<p>HC1</p> <p>HC4</p> <p>HC3</p> <p>HC3</p> <p>HC2</p> <p>HC1</p> <p>HC1</p> <p>HC1</p> <p>HC4</p> <p>HC1</p> <p>HC1</p> <p>HC3</p> <p>HC4</p> <p>HC4</p> <p>HC2</p>	15(18.3)

Pain	<p>I can't exercise due to pain</p> <p>I have pain in my back</p> <p>My feet hurt when I exercise</p> <p>I have knee pain</p> <p>When I walk I get muscular pain.</p>	<p>HC2</p> <p>HC2</p> <p>HC3</p> <p>HC1</p> <p>HC4</p>	5(6.1)
Q4: General comments			
No response			62(75.6)
Diet advice	<p>I suggest to add diet advice</p> <p>What about diet in diabetes care?</p> <p>What can I eat when I exercise?</p> <p>Can we have more advice on diet?</p> <p>Who can give us more diet advice?</p> <p>I like to perform PA but not sure of what to eat?</p> <p>How can I lose weight from PA and diet?</p> <p>I feel so tired to do any PA if I don't eat a proper meal. What can I do?</p> <p>Is it OK to exercise and cut down sugars?</p> <p>I don't understand what to eat if I exercise</p> <p>It is important to know the proper diet</p> <p>Why not including similar intervention to promote healthy diet</p> <p>I want to know more about the proper food in diabetes</p>	<p>HC2</p> <p>HC1</p> <p>HC3</p> <p>HC4</p> <p>HC3</p> <p>HC1</p> <p>HC2</p> <p>HC2</p> <p>HC3</p> <p>HC1</p> <p>HC3</p> <p>HC2</p> <p>HC2</p> <p>HC1</p> <p>HC4</p>	15(18.3)



	How can PA work without proper diet advice?  I suggest to include diabetes diet in future studies		
Project sustainability	Keep the project don't stop  I want to keep pedometers  Can we continue the WhatsApp communications	HC3  HC4  HC1	3 (3.7)
Similar project for children and all	Develop similar projects for children  Develop similar projects for the public	HC3  HC1	2(2.4)

### Appendix 9.5: Quotes from the POs (open questions exit survey):

Themes	Responses (quotes)	POs number	Numbers (%)
Q1: Topic which require more information			
No response			4 (25)
physical activity Behaviour change techniques	<p>We need more physical activity training especially on the behaviour change techniques</p> <p>I think the behaviour change techniques are difficult to understand, we need more training</p> <p>It's difficult to translate the behaviour change techniques from English to Arabic. A training manual may be needed</p> <p>What are the behaviour change techniques and how to apply them in promoting physical activity in diabetes care?</p> <p>Where can we get more training on applying the physical activity behaviour change techniques in diabetes care?</p> <p>Can we implement behaviour change techniques in all lifestyle initiatives?</p> <p>Where can we get an extensive training on behaviour change techniques?</p> <p>I suggest to have master trainers in physical activity behaviour change techniques</p>	<p>PO1</p> <p>PO4</p> <p>PO1</p> <p>PO8</p> <p>PO5</p> <p>PO12</p> <p>PO9</p> <p>PO2</p>	8 (50)
physical activity measurement tools	<p>Can we attach replace accelerometers with other devices?</p> <p>What is the purpose of the questionnaires?</p> <p>How can we shorten the physical activity questionnaire?</p>		4 (25)

	Can we use a simpler physical activity questionnaires?		
Q2: Challenges to delivering the intervention			
Physical challenges	No dedicated room/space	PO3	9 (56.2)
	Busy clinics	PO2	
	No physical activity facilities	PO16	
	Lack of staff	PO3	
	Staff turnover	PO6	
	Consultation rooms are small	PO7	
	The setting in the clinics is not welcoming as there are too many furniture	PO1	
	Diabetes clinic require more supportive physical activity tools	PO2	
		PO6	
	There is no proper waiting areas for patients and their families to wait		
Logistical challenges	Consultations are too long sometimes	PO12	7 (43.8)
	Long questionnaires	PO16	
	Managing appointments was difficult	PO5	
	Handling accelerometers was difficult	PO10	
	Participant don't attend on time	PO3	
	It is sometimes difficult to demonstrate effective physical activity without appropriate tools	PO10	
		PO8	
	Adherence to appointments		
Q3: General comments			
No response			2(12.5)

Sustaining the intervention	WhatsApp communications may be useful for future physical activity interventions	PO8	12(75)
	Include physical activity in the Health information system	PO3	
	Can we keep the pedometers?	PO4	
	This project can be a good start for integrating physical activity in primary health care	PO1	
	Can we continue the physical activity consultations	PO7	
	We need to train everyone in the health centre	PO1	
	All staff working in the health centres may benefit from training on PA consultations	PO10	
	Keep the same staff don't transfer or mobilize	PO16	
	Implement this project in all health centres	PO12	
	This project needs to be monitored and evaluated similar to all other primary care public health programmes	PO7	
	A specific budget needs to be allocated to maintain physical activity services in diabetes care	PO3	
	Involve all stakeholders	PO11	
physical activity facilities	We need information on the available physical activity facilities in the nearby community	PO5	2(12.5)
	Where can we refer the patient to for physical activity?	PO6	